QUALITY MANAGEMENT PLAN

USEPA REGION 10

US ENVIRONMENTAL PROTECTION AGENCY- REGION 10

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Seattle Washington 98101

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APPROVAL PAGE

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ACRONYMS

AHERA	Asbestos Hazard Emergency Response Act
AIRS	Aerometric Information Retrieval System
ANSI	American National Standard Institute
CADRE	Computer-Aided Data review
CAFO	Concentrated Animal Feeding Operations
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFO	Chief Financial Officer
CLASS	CLP Analytical Services Support Contract
CLP	Contract Laboratory Program
CO	Contract Officer
DQOs	Data Quality Objectives
DRA	Deputy Regional Administrator
EDCA	Environmental Data Collection Activities
EIU	Environmental Information Unit
EPA	US Environmental Protection Agency
EPCRA	Emergency Prevention and Community Response Act
ESAT	Environmental Services Assistance Team
FASP	Field Analytical Support Project
FCO	Funding Control Officer
FMFIA	Federal Managers Financial Integrity Act
FRC	Federal Record Center
FSP	Field Sampling Plan
FTE	Full Time Employee
FWS	Fish and Wildlife Services
GPO	Government Printing Office
GPRA	Government Performance & Results Act
H&S	Health and Safety
HQ	EPA Headquarters
HQQS	EPA HQ Quality Staff
HRO	Human Resources Office
HRS	Hazard Ranking Scoring
IAGs	Inter-agency Grants
IFBs	Invitation for Bids
IPA	Inter-governmental Personnel Agreement Act
IRM	Information Resources Management
IRU	Information Resources
IT	Information Technology
LIMS	Laboratory Information Management System
LT-2 SWTR	Long term enhanced Surface Water Treatment Rule
MEL	Manchester Environmental Laboratory
MOA	memorandum of Agreement
MPA	Microscopic Particulate Analysis
NAMS	National Air Monitoring Stations
NEPA	National Environmental Policy Act
NERL	National Exposure Research Laboratory
NESHAPS	National Emissions Standards for Hazardous Air Pollutants,
NIST	National Institute of Standards and Technology
NPDES	National Pollution Discharge Elimination System

NPL	National Priority Listing
NSPS	New Source Performance Standards
OAQ	Office of Air Quality
OCEC	Office of Communication Education and Change
OCREEJ	Office for Civil Rights, Enforcement and Environmental Justice
ODs	Office Directors
OEA	Office of Environmental Assessment
OEC	Office of Ecosystems and Communities
OECL	Office of Environmental Cleanup
OEI	Office of Environmental Information
OEMI	Office of Environmental Management and Information
OMP	Office of Management Programs
ORC	Office of Regional Counsel
OW	Office of Water
OWCM	Office of Waste and Chemicals Management
PAHs	Polyaromatic Hydrocarbons
PBDPEs	Polybrominated Diphenyl Ether
PCBs	Polychlorinated Biphenyls
PED	PM2.5 Evaluation Database
PEP	Performance Evaluation Program
PES	Performance Evaluation Samples
POs	Project Officers
PRP	Potentially Responsible Parties
PRs	Purchase Requisition Form
PSD	Prevention of Significant Deterioration
QA	Quality Assurance
QAARWP	QA Annual Report and Work Plan
QAC	Quality Assurance Coordinator
QAPP	Quality Assurance Project Plan
QAS	Quality Assurance Staff
QBS	Quarterly Blind Samples
QC	Quality Control
QM	Quality Management
QMP	Quality Management Plan
QRT	QA Review Team
QS	Quality System
QSRs	Quality System Reviews
RA	Regional Administrator
RAC	Remedial Action Contract,
RCRA	Resource Conservation and Recovery Act
RFBs	Requests For Bids
RFPs	Requests For Proposals
RPMs	Regional Project Managers
RPOs	Regional Project Officers
RQAM	Regional QA Manager
RSCC	Regional Sample Control Coordinator
SAF	Sample Alteration Form
SAP	Sampling and Analysis Plan
SAS	Special Analytical Services
SARA	Superfund Amendments and Re-authorization Act
SDG	Sample Delivery Group

SDWA	Safe Drinking Water Act
SIRMO	Senior Information Resources Management Official
SLAMS	Stae and Local Air Monitoring Stations
SOPs	Standard Operating Procedures
SRM	Standard Reference Materials
SRC	Superfund Record Center
SRO	Senior Resource Official
START	Superfund Technical Assessment & Response Team
STORET	Store It and Retrieval
SWTR	Surface Water Treatment Rule
TEP	Technical Evaluation Panel
TM	Task Monitor
TO	Tribal Office
TSCA	Toxic Substances Control Act
TSR	Technical Systems Review
UATMP	Urban Air Toxics Monitoring Program
UICP	Underground Injection Control Program
USGS	US Geological Survey
WAM	Work Assignment Manager
WDOE	Washington Department of Ecology
WMBE	Women and Minority Business Enterprise
WP	Work Plan
WPP	Work Projection Plans
WPPES	Water Pollution PE Sample

DEFINITIONS

The following definitions are essential in understanding the roles, responsibilities, policies, and procedures outlined in this document:

The term **Regional Program Managers** shall be used in this document to include all supervisory and management personnel (e.g., Unit Manager or Office Director).

The term **Regional Project Managers** and **Regional Project Officers** shall be used in this document to include all personnel responsible for overseeing environmental data collection activities. This shall include, but not be limited to: Remedial Project Managers, Site Assessment and Investigation Managers, Work Assignment Managers, Task Monitors, Delivery Order Officers, On-Scene Coordinators, permit writers, compliance personnel, investigators, project officers, etc.

The **Regional Quality Assurance Manager** (RQAM) has the delegated authority for implementing, managing and overseeing regional quality management policies, practices, and requirements. The RQAM is also responsible for overseeing the implementation of the Agency-wide QA program, including grants, contracts, formalized and interagency agreements.

Quality Management System is a structured and documented management system describing the quality assurance policies and procedures for ensuring that (1) environmental data are of known and documented quality and (2) environmental technology is designed, constructed and operated in a manner to produce the desired environmental results.

Quality Assurance is an integrated quality system comprised of quality assurance and quality control activities including but not limited to the process of project planning, development, implementation and assessment to ensure that environmental data of known, documented and needed quality are generated.

Quality Control is the overall system of technical activities that measure the performance of a process or a Quality Assurance (QA) element against defined standards to ensure that the process or QA element meets the pre-defined standards of the customer.

Quality Assurance Project Plan is a critical planning document for a project or task, describing how data collection and utilization activities are planned, developed, implemented and assessed with the incorporation of appropriate quality system to ensure that the generation of data will meet its intended use.

Data Quality Objectives are qualitative and quantitative goals that specify project or study objectives, define the appropriate type of data needed and the tolerable levels of decision error in data collection and generation activities.

Internal Data is the data generated for and by Region 10 programs with regional staff having primary responsibility for decision making. Region 10's quality assurance management system requirements apply to these data. Regional contracts which produce environmental data fall into this category if Region 10 staff are the primary decision makers.

External Data is the data generated by organizations other than Region 10 which are funded by EPA through grants, cooperative agreements, contracts and/or interagency agreements. Overall EPA quality assurance requirements for financial assistance agreements covered in 40 CFR 30.54 and 31.45 apply to these data.

INTRODUCTION

This Quality Management Plan is prepared to document the quality assurance policies, procedures, responsibilities and management systems that are in place for the implementation of the Quality Assurance Management System in Region 10. The purposes of this QMP are three-fold, i.e., (1) to provide a logical connection between Region 10's and the Agency's quality management policies (2) to provide the framework and criteria for establishing the program's Quality Management (QM) and Quality System (QS) within the Region and (3) to assist the Regional Program/Project Officers and Managers (RPOs/RPMs) in the uniform implementation of this QMP, quality assurance, and quality control (QA/QC) requirements for the Region's Monitoring Programs, Grants, Contracts, Cooperative Agreements, and other Interagency Agreements. This document is prepared in accordance with the *"EPA Requirements for Quality Management Plans", EPA QA/R2, March 2001* (Appendix B).

1 MANAGEMENT AND ORGANIZATION

1.1 Mission and Organization

Region 10's mission is to protect and restore the environment of the Pacific Northwest and Alaska for present and future generations. To achieve this mission, the Region relies on its own environmental measurements and those collected by other Governmental agencies and regulated parties to make decisions affecting public health and the environment. Region 10's QA policies and activities regarding environmental data are consistent with the requirements of EPA Order 5360.1A2 and other Agency mandates. The responsibility to implement the quality system rests with the Regional Quality Assurance Manager (RQAM) and all Regional Managers and staff involved in environmental data collection activities. Oversight responsibilities for developing and overseeing the quality system resides with the RQAM. The QM and QS documented in this QMP describes the management and technical activities necessary to plan, implement, assess and ensure the effectiveness of the QA/QC operations applied to the environmental data collection programs in Region 10. This QMP further defines the program management's roles, responsibilities and authorities for implementing the Region's QM system.

Region 10 is comprised of 13 Program Offices located in Seattle, Washington and one Operations Office for each State: Washington, Alaska, Oregon and Idaho. The authority and responsibility for managing the QM program within the Region is assigned by the Regional Administrator/Deputy Regional Administrator (RA/DRA) to the RQAM. The RQAM, is a non-supervisory program management position located in the immediate office of the Office of Environmental Assessment (OEA), reporting directly to the Office Director (DO). The RQAM also has authority to go directly to the RA/DRA and find resolution to critical QA problems and disputes. The RQAM functions independently of direct environmental data generation, model or technology development responsibility. The RQAM has sufficient technical, management expertise and authority to provide independent

oversight of and assure the implementation of the Region's QS in the environmental programs.

Region 10's organizational structure is shown in Figure 1. Identification of each Regional Program's role covered by the QM requirements are described below:

Office of Environmental Assessment (OEA) has the management responsibilities for the uniform implementation of the QS mandated by this QMP. The RQAM is organizationally located in OEA. OEA's technical specialists provide specialized technical support in project planning, data , ecological and human health risk assessments, facility inspections and compliance, economics/financial analysis, conduct special studies in support of OEA initiatives and analysis of environmental samples. OEA provides oversight to EPA's special projects and external environmental monitoring activities. When requested, OEA also prepares Quality Assurance Project Plans (QAPPs) and/or Standard Operating Procedures (SOPs) for some of the monitoring and measurement activities that the programs conduct. OEA's organizational structure is shown in Figure 2.

Office of Air Quality (OAQ) has the lead program management responsibilities for the State/Local Air Monitoring Station/National Air Monitoring System (SLAMS/NAMS), stationary source, New Source Performance Standards (NSPS), National Emissions Standards for Hazardous Air Pollutants (NESHAPS), Asbestos Hazard Emergency Response Act (AHERA), mobile source, Particulate Matter (PM) 2.5 Performance Evaluation Program (PEP), Urban Air Toxics Monitoring Program (UATMP), Aerometric Information Retrieval System (AIRS) database and the Clean Air Act part of the Toxic Substances Control Act (TSCA) programs. OAQ manages a portion of the Regional Federal grants and contract fund processes. OAQ ensures that QM matters are reflected in budgets, program plans, and work/operating and project plans. OAQ serves as the program authority for all air environmental monitoring activities within the geographical boundaries of Region 10. Data arising from these activities are the product of efforts, both internal and external to the Region. OAQ provides program oversight while the RQAM provides QA oversight of external environmental air monitoring programs.

Office of Ecosystems and Communities (OEC) has the program management responsibilities for the pesticides, aquatic and marine environments, natural resources management, wetlands, non-point source Water Quality Program under the Safe Drinking Water Act (SDWA) and other National Environmental Policy Act (NEPA) programs. OEC ensures that QA matters are reflected in the Office's budgets, program plans and work/operating plans. OEC serves as the technical and program authority for all of the programs listed above within the geographical boundaries of Region 10. Data arising from these programs are the product of efforts, both internal and external to the Region. OEC provides program oversight while the RQAM provides QA oversight of external environmental monitoring activities.

Office of Environmental Cleanup (OECL) has the program management responsibilities for the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Superfund Amendments and Re-authorization Act (SARA), and Emergency Response Programs. OECL ensures that QA matters are properly reflected in budgets, program plans, contracts, permits, inter-agency agreements (IAGs) and work, operating and sampling plans. OECL serves as the technical and program authority for all Superfund and Emergency Response environmental monitoring activities within the geographical boundaries of Region 10. The data arising from these programs are the product of efforts, both internal and external to the Region. OECL provides program oversight while the RQAM provides QA oversight of external environmental monitoring programs.

Office of Waste and Chemicals Management (OWCM) has the program management responsibilities for the Resource Conservation and Recovery Act (RCRA), TSCA, and the Emergency Prevention and Community Response Act (EPCRA). OWCM is responsible for permitting and compliance, as well as, enforcement for facilities disposing, producing, transporting and/or storing hazardous waste. OWCM manages Federal grants and contract funds. OWCM serves as technical and program authority for all RCRA environmental monitoring activities within the geographical boundaries of Region 10. The data arising from these programs are the product of efforts, both internal and external to the Region. OWCM provides program oversight while the RQAM provides QA oversight of external environmental monitoring programs.

Office of Water (OW) has the program responsibilities for the public water supply, ambient surface and groundwater, underground injection control, estuarine waters, off-shore discharge, and domestic and industrial wastewater treatment programs. OW is responsible for permitting and compliance, as well as, enforcement for water stationary sources, domestic and industrial treatment facilities. OW manages Federal grants and contract funds. OW ensures that QA matters are properly reflected in budgets, program plans, contracts, permits, Inter-agency Grants (IAGs) and work/operating plans. OW serves as the technical and program authority for all water related environmental monitoring activities within the geographical boundaries of Region 10. The data arising from these programs are the product of efforts, both internal and external to the Region. OW provides program oversight while the RQAM provides QA oversight of external environmental monitoring programs.

Office for Civil Rights, Enforcement and Environmental Justice (OCREEJ) is responsible for overall direction and management of the civil rights program, the enforcement and compliance assurance program, as well as the environmental justice program in Region 10. Other office responsibilities and functional areas include the Women and Minority Business Enterprise (WMBE) which ensures that recipients of EPA financial assistance award a fair share of contracts and/or procurement to small, minority, and women's business. The office also works promoting selected "beyond compliance" activities such as Performance Track and Environmental Management Systems.

Office of Regional Counsel (ORC) serves as a central legal office providing regional and national leadership in the environmental arena, particularly in the area of enforcement.

Office of Communication Education and Change (OCEC) coordinates and facilitates the exchange of environmental information with external customers, nurtures external relationships, supports and challenges internal customers to implement innovative approaches to achieving the Region's mission and goals, disseminates timely, accurate, relevant and useful information to Region 10 management and staff, the press, congressional delegations, international partners, residents of impacted communities and the general public, implements the national environmental education and children's health programs, supports adaptive and innovative change by developing, fostering and creating conditions to break through existing organizational and personal barriers in order to achieve extraordinary environmental protection.

Tribal Office (TO) ensures that the Region's commitment to work with the federally recognized Tribes of the Pacific Northwest and Alaska, on a government-to-government basis, to protect, restore and preserve the environment for present and future generations is implemented. This office has the following responsibilities: direct implementation of environmental protection programs where EPA has not approved a tribe to run a federal program, oversight responsibility both within and outside of Indian country concerning activities that affect tribal resources and strengthen tribal governments' management of environmental programs by assisting tribal governments to build the capacity to determine the future quality of their environment. TO provides program oversight for their environmental data collection activities while the RQAM provides QA oversight of their internal and external data collection activities.

Office of Management Programs (OMP) provides strategic leadership to the Region, and ensures systems are in place to manage Regional human and material resources. This office assures implementation of comprehensive program for resource focusing and that the Region's financial resources are used effectively and efficiently. It also establishes and monitors systems and controls to ensure the Region's Federal Managers Financial Integrity Act (FMFIA) process is in compliance with Agency policies and procedures and that the regional contracts, grants, and procurement are in the best interests of the government. OMP oversees the Region's infrastructure and operations programs. The Deputy Regional Administrator (DRA) manages all functions within this office and provides leadership, planning, guidance, and coordination for all OMP, including budget, space utilization, personnel, and other areas related to day-to-day operation of the Office and is responsible for continuity of operations planning.

Office for Environmental Management and Information (OEMI) performs the following function: Supports the Region's mission to protect public health and the environment by effectively fusing progressive strategic planning and management efforts with the collection and integration of high-quality, comprehensive environmental information. OEMI goals include focusing the Region's

resources on issues of immediate and projected priority concern, informing operational decision-making, and improving results-based performance. The Office, working with the Region's internal and external stakeholders and partners, establishes and oversees information-related policies, procedures, and tools that reflect and effectively address the concerns and interests of Regional managers and staff, Local, State, and Federal governments, Tribes, the regulated community, interest groups, and the general public. In brief, OEMI has three major emphases, involving the management of: environmental information, Information Technology (IT) infrastructure, and strategic planning, performance measurement, and innovation processes.

EPA State Operations Offices (Alaska, Idaho, Oregon, Washington) represent the Regional Administrator on State matters and provide leadership, coordination, and liaison with the officials of each State's environmental agency, Tribes, and other Federal, State, and Local organizations. The State Operations Offices operate and are supervised by the Regional media Program Unit Managers. It is incumbent upon the media Programs to ensure that the personnel in the Operation Offices are up-to-date and capable of ensuring that all of their environmental data collection activities (EDCAs) integrate the Regional QA program requirements. The RQAM's role in this scheme is to coordinate with Programs to determine if QA training is required in the Operations Offices to keep the personnel abreast with new Agency QA Guidances and requirements. State Operations Offices perform Program specific functions according to the Programs'approved work plans such as facility inspections, permits, outreach, Superfund site clean-up and management, ecosystem, geographic work, and multi-media coordination. The State Offices shall be responsible for preparing and submitting QAPP for each EDCA they conduct to the Regional media Programs for eventual RQAM review, comments and approval/disapproval. The plans shall be developed according to appropriate National and Regional QM requirements and specifications.

Figure 1- Region 10's Organizational Chart

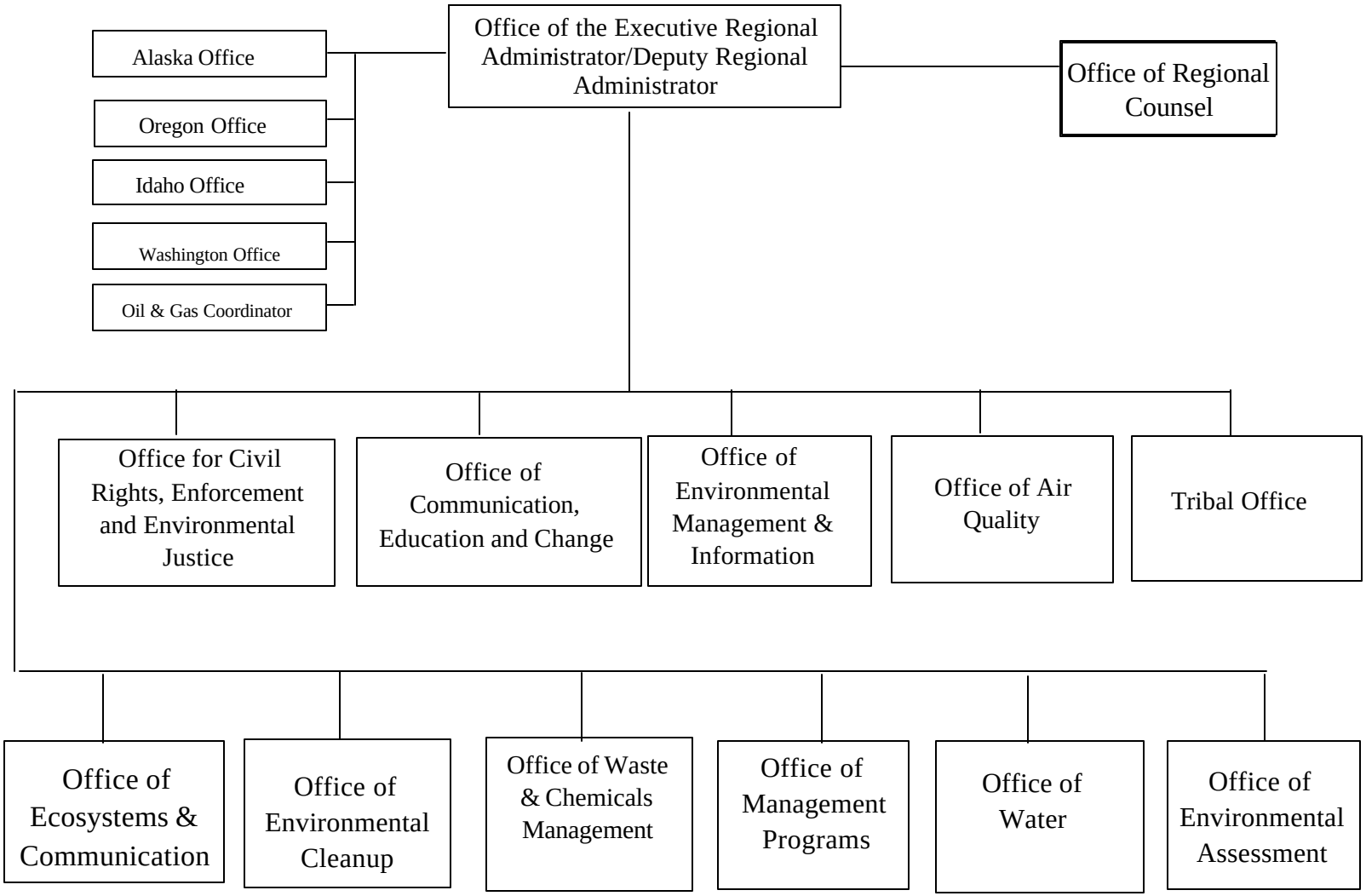
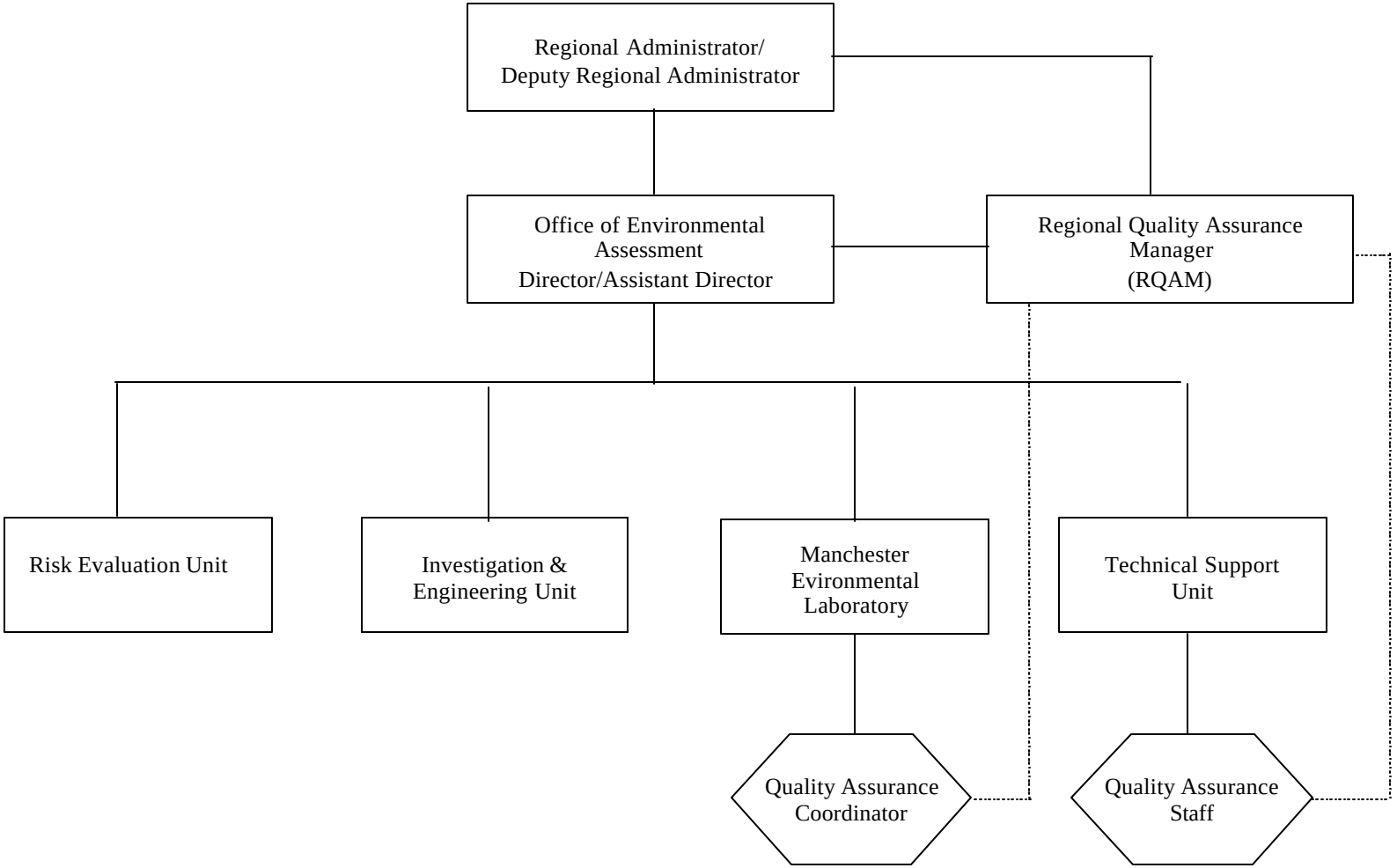


Figure 2 - Office of Environmental Assessment Organizational Chart



1.2 Quality System Roles, Responsibilities and Authorities

The overall responsibility for the QA Program in Region 10 rests with the Regional Administrator (RA), who is committed to ensure that QA is an identifiable activity with adequate resources allocated for accomplishment of the program and the regional goals in the development and execution of all projects and tasks involving environmentally related measurements, both in-house and extramural. The responsibility for planning, oversight and policy recommendations is contained in the performance standards of the RQAM.

Regional Administrator/Deputy Regional Administrator (RA/DRA). The overall responsibility for the development, implementation, and continued operation of the region's QM resides with the RA/DRA. The RA/DRA are committed to ensure that QA is an identifiable activity within the region and that adequate resources are allocated for the accomplishment of the program and Regional goals in the development and execution of all projects and tasks involving environmentally related measurements, both in-house and extramural EDCAs. The DRA manages all functions within the OMP office and serves as the Region's Senior Resource Official (SRO), Chief Financial Officer (CFO), and Senior Information Resources Management Official (SIRMO). The RA/DRA provide leadership, planning, guidance, and coordination for all OMP, including budget, space utilization, personnel, and other areas related to day-to-day operation of the office and is responsible for continuity of operations planning. The RA's/DRA's responsibilities are as follows:

- Ensure that all regional components and programs comply fully with the requirements of the QA Order 5360.1A2 and the specifications of the Quality Manual, including the timely preparation of a QMP for the Region, implementation of an effective QM specified in the QMP and the submission of QA Annual Report and Work Plan (QAARWP) to the Office of Environmental Information (OEI).
- Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals.
- Ensure that all applicable environmental programs delegated to State, Tribal and Local governments, or performed by organizations outside EPA pursuant to EPA regulations and requirements, comply fully with the requirements of the QA Order.
- Ensure that adequate and appropriate QM, QA and QC training are provided to Regional management and staff.
- Ensure that Federal agencies and State, Tribal and Local governments performing EDCA under assistance agreements with EPA have sufficient QM and QA/QC training in order to perform the work successfully.
- Ensure that periodic regional Quality System Reviews (QSRs) of regional organizational units, States, Tribes, Local governments and other organizations performing EDCA for and by the Region are conducted to determine the effectiveness of their mandatory QM

and QS implementation.

Regional Quality Assurance Manager (RQAM). The authority and responsibility for managing the QM program within the Region is assigned by the RA/DRA to the RQAM.. The RQAM, is a non-supervisory program management position located in the executive office OEA, reporting directly to the Office Director (OD). The RQAM also has authority to go directly to the RA/DRA and find resolution to critical QA problems and disputes. The RQAM functions independently of direct environmental data generation, model development or technology development responsibility. The RQAM has sufficient technical, management expertise and authority to provide independent oversight of and assure the implementation of the Region's QS in the environmental programs. The RQAM has the authority to access and utilize the QA staff located in the Technical Support Unit (TSU), the other technical specialists within OEA and the Environmental Services Assistance Team (ESAT) contract as needed to support the Regional QM and QS program. This provides the RQAM with sufficient authority and technical resources to assure the independent implementation and oversight of the regional quality system within OEA and throughout the Region. The RQAM shall have the following responsibilities:

- Serves as principal advisor to the RA, DRA and ODs on all matters concerning the Agency's QS.
- Recommends policies and procedures for the management of QA/QC within the Region.
- Serves as the official regional contact for all QA matters and communications from OEI Quality Staff, other Regions and Headquarters personnel, the States and Indian Nations and the private sector.
- Attend QA meetings to keep abreast of QA issues affecting the Region and Agency.
- Provides QA guidance and training to regional and state personnel in the Region.
- Responds to QA needs, resolves problems, and answers request for QA guidance and/or assistance.
- Assists Region 10 staff in the development of internal regional QAPPs. This includes participation in and/or review of the effectiveness and implementation of the project's established data quality objective (DQO) goals.
- Reviews, comments, and approves/disapproves of the programs' QAPP, SOPs and SOWs used for internal and external Regional data operations, except in situations where the State, Tribal and Local agencies have been granted QA-related document approval authority through the RQAM's approval of the organization's QMP.
- Reviews the effectiveness of the implementation of the program's selected QAPP and determines the adequacy of the data generated for its intended use.
- Assists the regional programs in integrating EPA QA Program requirements into the States, Tribal and Local organization's grants and into contract/IAG scopes of work.
- Assists the States, Tribes and other grantees in the development of QMPs and QAPPs.
- Coordinates and conducts routine and periodic Quality and Technical System Reviews (TSRs) of the Region's internal and external environmental monitoring programs.

- Serves as a Technical Evaluation Panel (TEP) member for Regional procurement where EDCAs are involved.
- Develops and revises the Regional QMP.
- Prepares and submits QAARWP to regional Management and OEI.
- Participates in OEI's Quality System Review (QSR) of Region 10's QA activities.
- Provides guidance and training on QA policies and procedures to regional staff, States, Tribes and Local organizations involved in data collection activities.

Office Directors/Regional Program Managers ODs/RPMs are responsible for ensuring that their internal and external data collection activities are conducted in accordance with the Agency's and Region 10's QA policy. Daily QA management is delegated to the appropriate line managers (i.e., Unit Managers). The line managers are responsible for the implementation of QM procedures with his/her area of responsibility to ensure the acceptability of data generated and processed. The key responsibilities of Regional Program Managers are:

- Ensure that effective implementation of the Region's QM and other QA matters are reflected in monitoring budgets, program plans, and operating plans.
- Participate in the development of DQOs for monitoring activities.
- Review and evaluate internal and/or external monitoring QM and QA implementation and progress.
- Review and evaluate the quality of data generated by monitoring projects.
- Take corrective action as required by QA audits, assessments or reviews.
- Oversight of the RPM's implementation of the QM and QA activities.
- Report data quality problems to RQAM.
- Ensure that all staff are aware of the requirements of this QMP.
- Ensures that staff comply with this policy and the EPA Order 5360.1A2
- Request appropriate training for staff to comply with the Agency an Region's QA policies.

Regional Project Officers/Managers Regional Project Officers/Managers (RPOs/RPMs) are responsible for site specific internal regional EDCAs and are accountable for the management of the external EDCA assistance agreements. The RPOs/RPMs have the principal responsibility for ensuring that project data quality objectives are met. The key responsibilities of the RPOs/RPMs are:

- Ensure that the project is operating in accordance with the Agency and Region's QA policies.
- Prepare and/or direct the preparation of a QAPP for each project, submit to RQAM for review/approval except in situations where the project is funded through a State/Tribal continuing environmental program grant. If the State/Tribal agency has an approved QMP describing the QAPP review and approval process, that agency may be delegated the responsibility for these activities.
- Prepare and/or approve DQO specifications, and acceptance criteria for the projects,

unless the project is funded through a State, Tribal and Local agencies' continuing environmental program grants with an EPA and RQAM approved QMP.

- Overview the quality of data generated from external projects funded through financial assistance agreements as required.
- Coordinate project oversight through the use of QA system and performance audits of projects' QA activities.
- Coordinate review of external QAPP and SOPS. Submit the QA documents to the RQAM for review and approval/disapproval, except in situations where the State, Tribal and Local agency has review responsibilities under continuing environmental program grants.
- Take corrective action that may be required as a result of the audit findings.
- Report data quality problems to the RQAM.
- Attend Regional QA training provided by the RQAM or OEI in the Region.

Quality Assurance Staff (QAS). The QAS composed of experienced chemists and technical experts are authorized by the RQAM to review QA planning documents, provide comments and rationale for the recommend approval/disapproval of the document to the RQAM. They assist RQAM in the development, preparation and review of program and project site specific QAPPs. The QAS work consistently with the program and project managers to implement the regional QM activities as specified in this QMP. In addition, the QAS provide data validation and assessment of the internal and extramural data generated for the programs. The key responsibilities of the QAS are:

- Review Programs' QMPs, QAPPs, SOPs and SOWs used for the regional internal and external EDCAs and provide rationale and recommendations for approval or disapproval to the RQAM.
- Oversee and coordinate QA activities within the Region and provide updates to the RQAM. Advise the RQAM on changes needed to the Regional QMP.
- Coordinate program input for the Regional QAARWP preparation and submission of this document to the RQAM for review and subsequent submission to OEI.
- Consult with the RQAM, respond to QA/QC issues and problems, and requests for guidance or technical direction.
- Through the Regional Sample Control Coordinator (RSCC), coordinate sampling and analysis activities with the Regional Laboratory and the Contract Laboratory Program (CLP) and provide regional sample tracking numbers, custody seals and custody documentation to the field samplers.
- Serve as the Document Control Officer whose responsibility is to keep track of the workload of each QAS and technical specialist in the Project Tracking database. All of the work requests accepted by the RQAM and/or QAS and other technical specialists shall be required to be entered and tracked in this database.
- Serve as the RPO for the Superfund's CLP. Provide technical direction, regional

management, oversight and authorize payment of the CLP laboratories used in EDCA in Region 10.

- Serve as the Work Assignment Manager (WAM) for the ESAT contract and functions involved in data validation and PM 2.5 PEP.
- Work with the Regional staff to develop and maintain an effective QA program.
- Conduct evidentiary audits of CLP data packages. Obtain program authorization and coordinate with the Superfund Record Center (SRC) the data storage transfer of old (≥6 months) CLP data packages to the Federal Record Center (FRC).
- Review data submitted through the Contract Laboratory Program (CLP) and by potentially responsible parties when requested.
- Assist the RQAM in the preparation, planning, coordination and training of the Regional staff, States, Locals, Tribes and other organizations involved in EDCAs in the region.

Quality Assurance Coordinator (QAC)

- Acts as technical advisor to the Lab management and staff in the formulation of QA procedures based on general policy provided by the RQAM..
- Ensures the implementation of QA policy, reviewing QA/QC data, and verifies that corrective action was taken when necessary.
- Prepares periodic reports to RQAM and management documenting the quality assurance data and performance of the laboratory.
- Coordinates the planning and implementation of the annual internal QA/QC management system audits of each of the analytical groups. Ensures that corrective actions resulting from these audits are addressed in a timely manner.
- Identifies the need for and coordinates revisions to the QA Manual and other QA documents.
- Initiates review of SOPs and coordinates necessary revisions.

Technical Specialists To ensure that a satisfactory level of QM and QA capabilities are maintained in Region 10, the RQAM shall have the authority to request and access technical assistance from the technical specialists within OEA. These personnel have expertise in specific areas such as: air, water, drinking water laboratory certification, compliance monitoring, field operations, chemistry, microbiology, environmental economics, biology, and data processing. Upon RQAM's request through the appropriate management, the technical specialists shall operate with and/or on behalf of the RQAM. The following duties may be assigned to the OEA Technical Specialists:

- Carry out Region 10 requirements for the Drinking Water Laboratory Certification Program.
- Conduct system and performance evaluations of SLAMS/NAMS and Prevention of Significant Deterioration (PSD) special studies monitoring networks.

- Conduct network reviews of regional air and water monitoring and modeling programs.
- Provide expert economics and financial analysis support to regional and national programs, international agencies and other Federal, State, Tribes, Local environmental organizations.
- Inform RQAM of the need for new or improved methods for sample collection, detection limits, data analysis and data assessment.
- Participate in technical assistance and training of State/Local, and private laboratory personnel in EPA methods, instrumental, and QA requirements.
- Review subordinate's and associates' data for QA before transmittal to the requester and finalization in the data system.
- Interact with other Agency programs on technical problems related to QM, QA, methods, instrumentation, and new programs.

1.3 Resources to Support the Quality System

The Region provides in-house and contracted expertise in the implementation of QA and other technical support in several scientific disciplines to all employees and programs in the Region. These support services include data needs assessment, data quality assessment, data analysis, evaluation and modeling provided by chemists, toxicologists, hydrologists, engineers, and others. Personnel providing these services are located in a number of Regional Program offices but most of them resides at the Office of Environmental Assessment (OEA).

Through workload models, EPA Headquarters (HQ) recommends funding levels for QM activities in each of the monitoring programs. The budgeting process reflects a policy of sharing resources between organizational units within the office. The OEA Director and the Program Directors involved in data collection activities jointly determine the level of resources needed to be allocated to OEA, to ensure program compliance and the implementation of the Region's QM and QS objectives. Region 10 ODs allocate the enabling QM resources to the OEA Director. The OEA Director, in turn, distributes these QM resources within OEA. A portion of the QM resources allocated to OEA is dedicated to the continuing support of the RQAM and the implementation of the QS within the boundaries of the Region with the balance distributed to the units responsible for providing technical support to the media Programs. The amount and distribution of QM resources in the Region, is not static, but a dynamic function of the changing emphases and priorities of the Agency monitoring programs. Therefore, staffing and travel resources allocated to the RQAM for each fiscal year varies and are explicitly identified in the QAARWP.

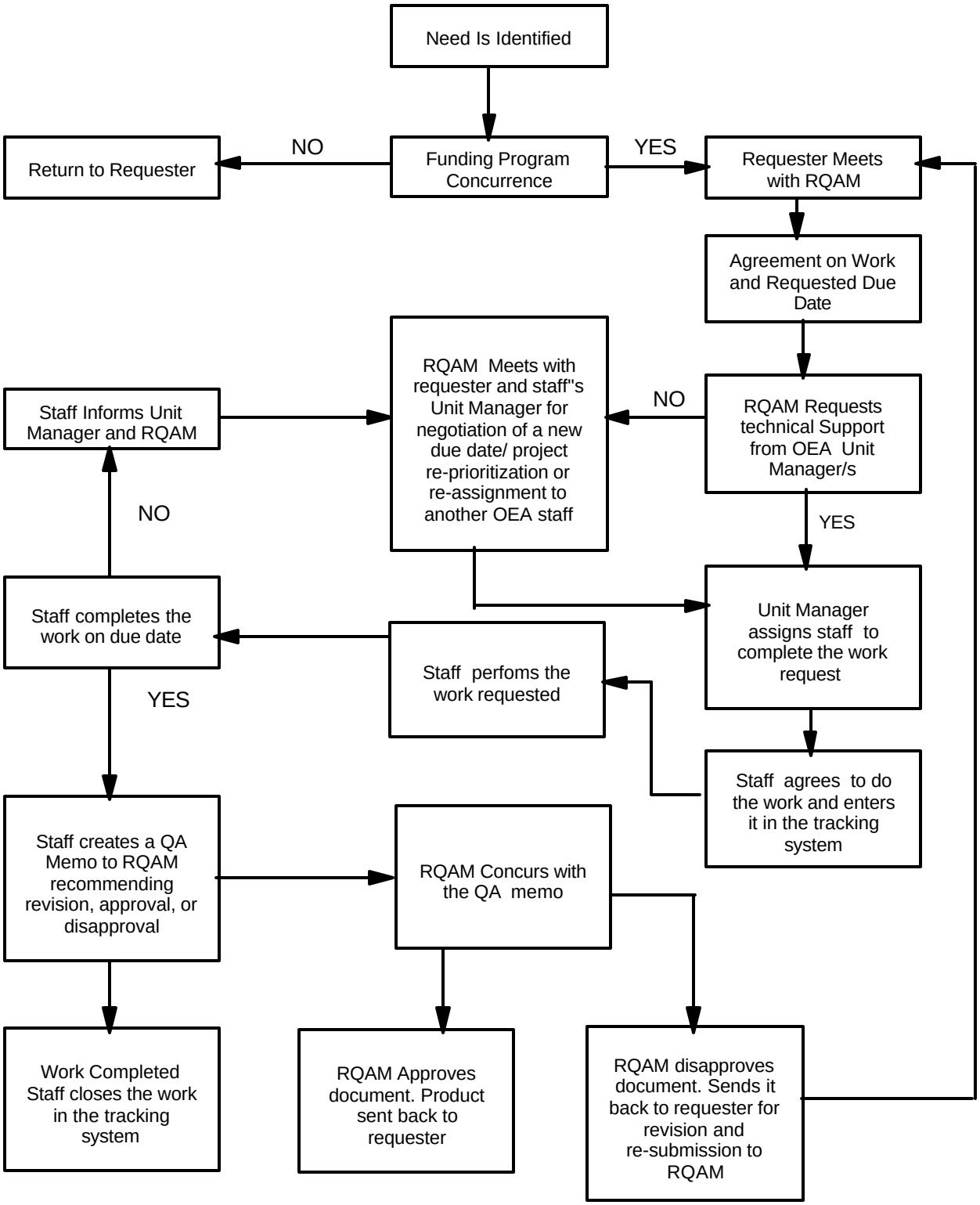
1.4 RQAM Workflow and Tracking Process

The RPOs/RPMs in the region shall follow the following workflow process when requesting technical support for the review and approval of QA documents from OEA:

- The need for QA support is identified by the requester.
- Prior to acceptance of any work, the funding program should always be informed and concur with the needs identified for QA support.
- The requester meets with the RQAM to discuss the details of the work that is requested, the estimated amount of time entailed and the completion due date for the product.
- The RQAM checks with the appropriate Unit Manager regarding the availability of expertise requested, conflicts of interest and current workload. If the Unit Manager's workload capacity is full, the RQAM, requesting official and Unit Manager will re-prioritize the work request and assign the request to the appropriate Unit staff.
- The Unit staff member who is assigned the work, enters it in the Lotus Notes Tacking System where it is assigned a tracking number by the tracking system document control coordinator.
- If there is no problem encountered, the work is completed by the due date, the product is submitted to the RQAM with a recommendation of approval or disapproval the work will be considered complete and closed in the tracking system. The RQAM will either approve or disapprove the product and return the work product to the requestor. If problems occur that will prevent the technical staff from completing the work on the required due date, the requestor will be informed the RQAM who will in turn inform the requester to establish a new due date. If an agreement on the new due date can not be reached, the requester will consult with the Unit Manager for resolution.
- The Unit Manager and RQAM will either re-assign the work request to another technical staff member or change the priorities of the technical staff member to meet the new due date. The tracking system is revised as necessary to reflect the new request and due date.

A flow diagram illustrating this process is shown in Figure 3.

Figure 3 - RQAM Workflow and Tracking Process



1.5 Independence of the Regional QA Manager

Order 5360.1A2 requires that the RQAM function independently of the programs involved in EDCAs and that this individual report to a senior manager having executive leadership authority for the organization. Order 5360.1A2 further requires that the office directly responsible for implementing the Region's QS be provided the authority and necessary resources to carry out the requirements of the QA order.

Sections 1.1 and 1.2 describes the independence of the RQAM.

1.6 Dispute Resolution

For those situations in which QA issues are in dispute, resolution shall be sought at the lowest management level possible. Such disputes may occur in situations involving technical issues (e.g., audits, data quality assessments) and management issues (e.g., QMP reviews, QAPP reviews, quality system reviews, data usability assessments).

All parties involved shall make every effort to resolve disputes through discussion and negotiation. If the agreement could not be reached at this level, the issue will be resolved by the RQAM and/or ODs. Also, the RQAM has direct access to the RA/DRA to resolve any potential conflict of interest posed by the RQAM's organizational location in OEA. QA issues or disputes with the program offices are presented by RQAM to the program's senior management for resolution. The RA/DRA has final dispute resolution authority on all Region 10 QA issues.

2.0 QUALITY SYSTEM

2.1 QA Goals and Policies

Region 10's basic QA goal is to ensure that all of the data produced and utilized for and by the Region's environmental data generation and utilization activities are scientifically valid, legally defensible, of adequate statistical quantity, of known precision and accuracy, and of acceptable completeness, representativeness, and comparability.

The following QA policies apply to all EDCAs conducted by Agency personnel, its contractors, grant and interagency agreement recipients:

- All of the appropriate QA planning document [QMP, QAPP, Sampling and Analysis Plan (SAP), Field Sampling Plan (FSP), or Work Plan (WP), etc.] individually or in combination as appropriate, will be developed and submitted for review and approval of the RQAM for each EDCA prior to the initiation of data collection.

- ! The intended use(s) and data quality objectives (DQOs) of environmental data will be defined prior to the collection of data, and identified in the appropriate QA planning document as defined by Agency policies and environmental regulations.
- ! Approved QA and QC procedures must be funded and integrated into all environmental data collection activities conducted within the Region.
- ! Projects and tasks involving environmental data collection and utilization activities will be accomplished in conformance with EPA approved QA planning documents.
- ! Oversight of data collection activities will be performed by the assigned RPOs/RPMs and deficiencies or problems promptly corrected.

2.2 Quality Assurance System for Internal and External Data Collection Activities

Oversight of the data generation activities in Region 10 shall be tailored to the nature of the EDCAs and the associated management and administrative system. Within the Region, QM operations and oversight fall into two categories of data collection activities, i.e., internal and external data collection activities.

Internal EDCAs are planned and performed by Region 10 personnel which support a variety of compliance, enforcement, audit and investigation activities. The RPOs/RPMs shall be responsible for ensuring that adequate QM and QA activities are integrated in the project's QAPP. The RPO/RPMs shall also be responsible for the submission of the QAPP and other QA-related document to the RQAM for review and approval prior to data collection. The RQAM and/or QAS will also be available to assist the program in the development of QAPP. The RQAM and/or QAS shall review and evaluate the implementation of the site specific QAPP during the operational phase of the monitoring activity. Selection of projects for QSR will depend on the following criteria: projects supporting litigation, high visibility projects, and requests from the RPOs/RPMs. Upon completion of the monitoring activity, the RPOs/RPMs with assistance from the RQAM shall assess the actual performance of the planned activities and subsequent results. The final project report shall contain the results of this assessment. Examples of QA requirements for internal data collection activities are provided below.

- A **continuous environmental EDCA** is one whose procedures do not change significantly from year to year, such as routine compliance sampling, or monitoring efforts performed under one of the regulatory programs. For this type of data collection activity, a WP and QAPP addressing the routine activities may be prepared. The WP and QAPP should be reviewed and approved by the RQAM. The QA planning documents shall be revisited and revised by the RPOs/RPMs to reflect the most current Agency QA requirements every five years and also in accordance with ANSI/ASQC E4-1994. The submission of an Addendum to the main QAPP for

RQAM's review and approval is required when significant changes in procedures, sample collection and/or organizational responsibilities occur.

- For the Superfund Program, the QA requirements and issues are **site-specific**. Such projects require a site and project specific QAPP, SAP and/or FSP which must be updated if the focus of the project changes significantly. Generally, a QAPP/SAP is used for discrete one time sampling events which has a distinct starting and ending date, such as a Brownfields investigation, whereas a WP/QAPP/FSP combination might be used for a more traditional Superfund remedial investigation which may be conducted over several years.

External EDCAs involve the expenditure of EPA funds in the form of grants, contracts, or formal cooperative agreements. The regulations for financial assistance agreements (40 CFR, Parts 30, 31, and 35) involving EDCAs require the inclusion of the applicant's QMP, WP and/or project specific QAPP in his/her grant application. The level and types of QA documentation that may be required with the grant applications depend on the nature of the grantee's project proposal. The responsible program Project Officers/Contract Officers (POs/COs) shall ensure that the required QA document is prepared and submitted to the RQAM for review, comment and approval before environmental measurements take place as part of the financial assistance agreement. In cases where the RQAM places conditions on the approval of the grant applications contingent upon submission of adequate QA documents prior to EDCA, the language in the memorandum of agreement (MOA) shall be mutually agreed upon by the POs/COs, the grants program and the RQAM. The acceptance of the grant by the grantee signifies their agreement to the grant conditions. The following are some of the extramural data collection activities funded by Region 10:

- **Interagency Grant agreements (IAGs)** such as with the U.S. Army Corps of Engineers are handled in a similar way to financial assistance agreements, although there are currently no CFR requirements in place concerning QA. For IAGs involving EDCAs, the RQAM and/or his designee may be requested by the program to review the funding memoranda and the QA documents submitted to determine the adequacy of the QA activities integrated with the Agency's QA program. For these reviews, the RQAM may provide comments and recommend approval or disapproval of the QA documents to the EPA program.

- **EPA Contracts** Management Manual (EPA Order 1900.2) and the Procurement Policy Notice (PPN) No. 01-02, "Guidance for Use of Higher-Level Contract Quality Requirements in Acquisitions," March 2001), require that all contract proposals which include environmental measurements shall be reviewed and approved by the RQAM for adequacy of QA/QC provisions through a QA memo submitted by the RQAM to

the PO and CO prior to data collection. All QA documents incorporated into a contract proposal or required by the contract must be reviewed by the RQAM. For contracts wherein QAPP and other QA documentation are not required (i.e., no EDCA involved) the PO signs the contract approval form which is then peer reviewed by the CO.

- **Other** external projects involve EDCAs that are periodically performed for the Region by other government agencies such as the US Geological Survey (USGS), Fish and Wildlife Services (FWS), Universities, etc. managed through formal cooperative agreements, and by parties in the private sector or the regulated community through administrative orders. EPA funds are not directly expended for these types of EDCAs, however, substantial EPA involvement may occur during conceptualization, scoping and performance of the project if the data will be generated for the Agency's or for compliance with the Agency's requirements. Before the Agency's use, the quality and usability of the environmental data generated by extramural projects are rigorously reviewed by RQAM. The RPOs or the RPMs shall work with the RQAM and ensure that adequate QA/QC activities are integrated with the EDCAs QAPP prior to data collection , generation and utilization. These QA/QC provisions shall be incorporated into the formal agreement, administrative order and/or other documents initiating the project.

Operations for Contracts, Interagency and Formalized Agreements

The originating Program Office shall notify the RQAM of all contracts and interagency formalized agreements involving EDCAs during the planning phase of the project. The CO and the RPOs/RPMs shall ensure that all requests for Bids/Proposals (RFBs/RFPs) or invitation for bids (IFB) will contain adequate and acceptable description of the QA requirements for contracts involving EDCAs. In addition, the RPOs/RPMs and CO shall ensure that a QA Review Form has been completed in accordance with 48 CFR Chapter 15, Part 1546.2 and EPA Order 1900, the Contracts Management Manual. The RPOs/RPMs shall also be responsible for including the RQAM as a technical evaluation panel (TEP) member on those contracts with a value of $500,000 or greater, if the contracts involve environmental measurements or technology. For interagency agreements, before the EDCAs commence, the RPOs/RPMs, RQAM and other involved federal agencies must agree upon the QA requirements for the project. The RQAM shall ensure that QMPs, QAPP and/or SOPs submitted are adequate and acceptable prior to recommending award of the contract or inter-agency formalized agreement. The QMP, QAPP and/or SOPs shall be reviewed, and as appropriate, approved by the RQAM. The RPOs/RPMs shall monitor and evaluate the efficiency of the implementation of these plans. Upon completion of the monitoring activities, the RPOs/RPMs with the assistance from the RQAM shall assess the quality and usability of the data generated from these EDCAs.

Quality Assurance Management Plan (QMP) Requirements for External Data Collection

The following QA review and approval procedures will be followed by those organizations submitting QMPs to Region10 for grants and cooperative agreements:

The QMP must address the QA elements specified in the *"EPA Requirements for Quality Management Plans", EPA QA/R-2, March 2001* or the most recent version. QMPs must include a description of the preparation, review and approval process for specific QAPPs covered by the organization's grant. All QMPs will be reviewed and approved by the RQAM. After the approval of the State, Tribal and Local agencies' QMPs, the authority to review the organization's site or project specific QAPPs and other QA planning document is transferred by the RQAM to the QA program of the organization. The approved QMPs shall be in effect for a period of no more than five years. Before the expiration date of the QMP, the organization shall revise their QMPs in accordance with EPA QA/R-2, March 2001 or the most recent version. The RQAM shall maintain a list and copies of the approved QMPs and their expiration dates.

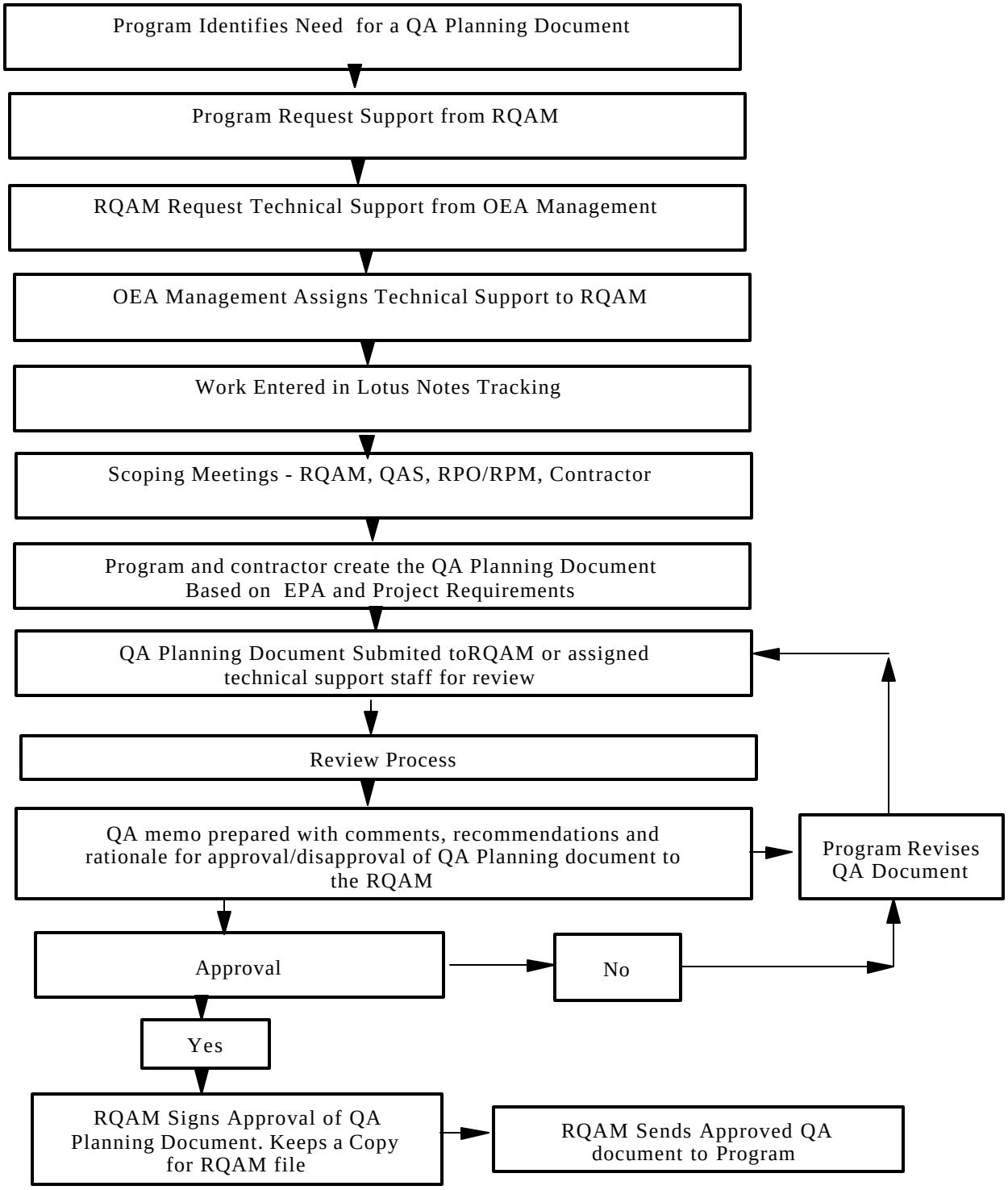
While State, Tribal and Local agencies are responsible for managing the QA programs under their grants, the Region retains the oversight responsibilities. The major oversight functions are WP, QAPP and SOPs reviews and program evaluations. RQAM's oversight functions include QMP review and approval and on-site QSRs of field and laboratory operations. State and other organization's program oversight is the primary responsibility of the individual EPA regional program office with input from the RQAM and other technical specialists.

QMP and QAPP Review and Approval Process for External Data Collection

The QAPP shall be prepared in accordance with the Agency required EPA-QA/R5 content and format, *"EPA Requirements for Quality Assurance Project Plans", Final, March, 2001*. The QAPPs must be reviewed and approved prior to the award of financial assistance by the RQAM and the appropriate RPOs/RPMs or designee(s). If the QAPP is not approved prior to financial assistance award, the assistance agreement will be conditioned to require an approved QAPP before data collection begins. If a grantee makes sub-awards/sub-contracts (either sub-grants or procurement) under an assistance agreement, they must ensure that the sub-awards meet the quality assurance requirements of 40CFR 31.45 and 30.54 as appropriate.

A flow diagram illustrating the development, review and approval process of QA planning document is in Figure 4 below. The process is discussed in section 9.1.

Figure 4. Preparation, Review and Approval Process of QA Planning Documents



2.3 Quality System Tools

To effectively manage and implement the Region's quality system and EDCAs, systematic planning, routine review and approval of project specific QA planning documents and assessment of the quality of data generated are required to establish a basis for corrective action, that may be needed. The following are the quality system tools used in planning and implementation of the Region's quality system:

Quality Management Plan (QMP)

Region 10 QMP contains the QM and QA policies and procedures governing Region 10's EDCAs. The document describes the Region's quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and evaluating EDCAs conducted. Region 10's management and staff are mandated in implementing these QA policies to ensure that all environmental data generated for or by Region 10 are of known and acceptable quality. The QMP is developed by the RQAM. The QMP is intended for use by all regional staff. A hardcopy of the QMP will be filed with each Regional Office and the Regional Library. The approved QMP will be accessible to all regional staff through the Regional InfoNet and to external organizations through the Region 10 home page. Regional Approval of Region 10's QMP requires signatures from the RQAM, OEA Director, RA and DRA. The QMP is then submitted to the Acting Assistant Administrator for the OEI, based on an affirmative recommendation by the Director of the Quality Staff (HQQS) for review and approval. The approval is valid for up to five years, pending changes to the organization or results from OEI's QSR.

A regional office or unit may be authorized by the RQAM to administer Region 10's QA policies and procedures, such as EPA's Manchester Environmental Laboratory (MEL) and the Superfund's Emergency Response Unit. The authority will be documented in the form of an RQAM approved Program QMP and/or QA Manual prepared according to the most current version of *"EPA Requirements for Quality Management Plans", EPA QA/R-2*. The Program QMPs must describe the management policies, objectives, procedures, organizational authority, roles, and responsibilities to be implemented by the unit or office to ensure that adequate QA/QC activities are integrated with all EDCAs and are of the type and quality needed for the data's intended use. The QMPs will be reviewed and approved by the RQAM for compliance with the QA order, EPA QA/R-2 document and the QMP Review Checklist. The QS specified in the unit or office's QMP or QA Manual shall be managed and implemented by the QACs. The QACs shall have the authority to review site/project specific QAPPs and other QA planning documents. Recommendations and rationale for the QA planning documents' approval/disapproval will be provided by the QACs to the RQAM.

Quality Assurance Annual Report and Work Plan (QAARWP)

The QAARWP is a summary of specific activities within the Region's QS. The Region's implemented QA activities of the previous fiscal year and the planned QA activities for the upcoming fiscal year are summarized in the QAARWP. The QAARWP will be prepared according to Chapter 4 of the most current version of the EPA Quality Manual (5360.1 A2) by the RQAM, and/or the QAS with inputs from the QACs and the RPMs. The QAARWP will also be used to identify minor changes or updates to Region 10's QMP. The QAARWP will be electronically submitted to the OD-HQQS by November 15 of each year (or other date as specified by the OD-HQQS). The electronic submission will be followed by a hard copy of the QAARWP signature page signed by the RQAM, OD-OEA, RA/DRA.

Quality System Reviews (QSRs)

A QSR is a qualitative evaluation of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. They are used to determine the effectiveness of, and adherence to, the quality system and the adequacy of resources and personnel provided to achieve and ensure quality in all activities. HQQS performs an independent QSR of Region 10's Quality System once every three years. Region 10's RQAM, QAS, QACs and/or other technical specialists comprise the Region 10's QSR Team. The QSR Team performs QSRs of the EPA MEL every two years (as required by the Regional Science and Technology (RS&T) Directors. QSRs of EPA laboratory contractors (ESAT), State, Tribes and other agencies shall be performed every three years. QSRs of internal programs and external organizations will be conducted by the QSR Team in a manner and frequency discussed in section 9.2.

Data Quality Objectives (DQOs)

Region 10 has integrated the development of DQOs for projects involving EDCAs into the normal process of project planning and design. Environmental data collection activities generally begin with project scoping, where project specific DQOs are determined in accordance with *"Guidance for the Data Quality Objectives Process," G-4, EPA/600/R-96/055, August 2000*, or most recent version, depending on the program involved. The sampling objectives, design strategy for optimizing the information obtained, and the acceptable levels of error (i.e., determining the number of samples to be collected to meet field and lab stated QA/QC criteria with available resources) are determined by the stakeholders, project managers, regional QA staff, risk assessors and other data users, in the project during this process. Project specific DQO goals are documented in ther site/project specific QAPPs prepared in accordance with the *EPA QA/R-5, EPA/240/B-01/003, March 2001* or most recent

version.

DQOs are comprised of qualitative and quantitative statements and goals developed to ensure that data of known and appropriate quality are obtained, to support specific decisions or regulatory actions. Over the years, EPA has refined the primary tool used to derive project specific DQOs. This is known as the DQO Process. The RQAM encourages the use of the DQO process through EPA's guidance documents: *Guidance for the Data Quality Objectives Process, EPA QA/G-4, August 2000* and *Data Quality Objectives Process for Hazardous Waste Sites, EPA QA/G4-HW, January 2000*.

Because the DQO process requires up-front planning with the project decision makers and stakeholders (e.g., data users, field and laboratory personnel, risk assessors, hydrogeologists, QA specialists, modeling experts, PRPs, community etc..), OEA and Superfund developed an organizationally- based project planning process specifically designed for the Superfund program's use. This QA planning document, in Appendix E, outlines the team approach to project planning, the roles and responsibilities of team members, the use of scoping meetings, the development and implementation of WPs and QAPPs, and the communication processes between team members and decision makers.

Quality Assurance Project Plans

A QAPP is a technical planning document that defines the project's DQOs, project management and functional organization, sample collection and field methodologies, chemicals of concern and reporting limits, laboratory and analytical methods, and the QA and QC activities incorporated in the QAPP to meet the DQOs of an environmental monitoring project. It is regional policy that all projects involving EDCAs, for and by the Region, shall have a QAPP reviewed and approved by the RQAM prior to the initiation of any data collection. This applies to all projects conducted or funded directly by the Region (termed internal), as well as, those for which the Region has only oversight responsibility (i.e. State-lead projects) or work to be performed by potentially responsible parties (mandated in consent orders or agreements), except in cases where a state or organization is the lead and is authorized by the RQAM, upon approval of the organization's QMP, to administer their own QS.

Responsibility for the preparation and submission of a QAPP lies with the RPOs/RPMs, whether he/she be the author or CO of the project. Preparation of the QA document shall involve all key participants in the project (QA, field, laboratory and project management). The RPOs/RPMs are responsible for soliciting the necessary technical assistance for the development and technical review of the QA document . The plan must be submitted to the RQAM, ideally, at least 30 days before the start of a project to afford sufficient time for review, revision and laboratory space coordination. It is the responsibility of the RPOs/RPMs that no EDCA starts before the QAPP has been approved by the RQAM. Figure 3 illustrates the process for the preparation, review, approval and implementation of QA planning documents.

If changes to the work in progress are necessary, the QAPP will need to be revised by the RPOs/RPMs and re-submitted to RQAM for review and approval. For those projects that entail long term operations, the QAPP should be reviewed as necessary by the RPOs/RPMs and/or RQAM to determine whether the plan is still applicable as written.

To ensure their effectiveness, the QAPP are required by the Agency to be prepared according to an approved format and the content requirements specified in the document *QA EPA/R-5 "USEPA Requirements for Quality Assurance Project Plans", Final Version: March, 2001,* (Appendix D) and the *"USEPA Region 10 Expanded Guidance for Preparing Quality Assurance Project Plans", Revision 1.0 dated 12/7/98* (Appendix E). The RQAM may, upon request and discussion, allow the combination of the QAPP with another QA document, such as a CERCLA QAPP combined with FSP and SAP or a RCRA Waste Analysis Plan, to save duplication of effort. In programs such as CERCLA, it is the preferred practice to combine the QAPP with the FSP and/or the SAP.

Generic Quality Assurance Project Plans

Generic QA Project Plans (Appendix F) were prepared by the RQAM to assist and provide field personnel and inspectors from the Office of Waste and Chemical Management, Office of Environmental Assessment and Region 10 State Offices with basic guidelines for the collection of samples, proper sample documentation and the use of correct sampling and analytical methodologies in the collection of "samples of opportunity" to verify and determine facility compliance. Samples collected will be sent to the regional laboratory, MEL in Port Orchard, WA. These Generic QAPPs were prepared in compliance with the EPA Order 5360.1A2, and in accordance with the Agency required *QA EPA/R-5 "USEPA Requirements for Quality Assurance Project Plans", Final Version: March, 2001,* and the *"USEPA Region 10 Expanded Guidance for Preparing Quality Assurance Project Plans", Revision 1.0 dated 12/7/98*.

The following generic QAPP are available for download from the this OEA H:drive ('R0Helens\Vol2\User\Share\OEA' (H:)

- Generic QAPP for RCRA Compliance Inspections
- Generic QAPP for Polychlorinated Biphenyl (PCB) Inspections
- Generic QAPP for the Concentrated Animal Feeding Operations (CAFO) Program
- Generic QAPP for Aquaculture NPDES Compliance Inspections
- Generic QAPP for Asbestos Inspection (AHERA, NESHAP & CERCLA)
- Generic QAPP for Underground Injection Control Compliance Inspections
- Generic QAPP for Stormwater Compliance Inspection

Standard Operating Procedures (SOPs)

Data collection procedures are standardized and published as written protocols for inclusion by reference in QA Program Plans, QAPP, SAPs, FSPs, contracts and similar documents, and for use as guidance and technical assistance documents. SOPs are prepared using the *"Guidance for the Preparation of Standard Operating Procedures (G-6)", EPA/240/B-01/004, March 2001*. SOPs require RQAM review and approval and are generally integrated as addendums to the QAPP submitted for RQAM review and approval. Program Specific SOPs are prepared primarily by four groups: EPA Region 10, when performing the lead in an EDCA, IAG recipients (such as the U.S. Army Corps of Engineers, U.S. Geological Survey, or U.S. Department of Energy), grantees (such as States, Tribes, and Universities) and PRPs, or other government entities (i.e., Federal facilities). The responsibility for preparing, updating and approving SOPs rests with these parties, although the Region 10 RQAM may comment or require SOP revisions/modifications depending on the nature of the project. These groups are encouraged by the Region to develop program-specific SOPS for recurring activities. The RQAM and/ designated technical specialist may assist in the preparation of site-specific and program-specific sampling and analytical SOPs. To avoid duplication of effort, an SOP prepared by one program may be utilized by another program, when appropriate, however, this will only be done with the permission of the originating party unless that party is under contract to EPA.

SOP revisions are prompted when the following situations occur and should be reviewed yearly:

a) Significant update/revision of procedures to improve method efficiency or changes due to instrument up-grades or new technologies.
b) Modification of methods or previously approved SOPS to address project or site-specific needs (e.g., need a lower detection limit for an analytical method).
c) Promulgation of new regulations or their revisions requiring the addition of new or revisions of existing SOPS due to more stringent and higher environmental standards.

SOPs affected by these criteria will need to be updated during the year of the change. The one year rule for revision and update may be waived on a case-by-case basis due to resource constraints involved or where the change is so minor that the quality of the data generated are unaffected. In these cases the minimum frequency for update will be every three years. When changes occur, EDCA related SOPs are revised and submitted to RQAM for review and approval as addendums to the QA planning documents. Periodic verification should be performed by the organization responsible for performing the EDCA to ensure that activities are conducted in accordance with SOPs.

Data Quality Assessment

The RQAM and QAS utilize three types of data quality assessment or evaluation tools (1)data completeness/evidentiary audit, (2) partial data validation and (3) full data validation. The RQAM and or designee performs these functions as requested by the Program Managers, and as resources permit. QA oversight is also provided by the RQAM and/or designee to EPA contractors when they are to be utilized for performing data verification and data validation.

The rigorousness of data review is successively increased with each type of data audit, based on project specific DQOs. A project file evidenciary audit consists of review and examination of the analytical project file documentation and determines (1) the accuracy of the document inventory, (2) the completeness of the file, (3) the adequacy and accuracy of the document numbering system, (4) traceability of sample activity, (5) identification of activity recorded on the documents, and (6) error correction methods.

A partial data validation involves the review of data for gross QA discrepancy and vulnerability. Effects on data quality and usability are determined by the RQAM and/or designee based on the sample results summary forms, the QC summary forms, the corresponding QC sample analytical data, chain-of-custody documentation and the Computer Aided Data Review Expert (CADRE) output. Because CADRE does not adequately address the data validation based on professional judgement, CADRE is only used as a reference and/or validation guide for partial data validation in Region 10. For data validation involving professional judgment, the data reviewers refer to the Regional Data Validation Guidelines. Partial data validation is usually requested by the program for the Targeted Brownfield Assessment Program, for the fast turn-around field analyses and other projects whose data are generated for program specific purposes only with no possibility of legal challenge or court litigation. For this type of data validation, a brief informal QA summary report discussing the quality and vulnerability of the data is prepared and submitted by the RQAM and/or designee to the requesting RPOs/RPMs.

A full data validation is a more in depth data verification and validation process which includes the review of the sample and quality control (QC) summary forms, the chain of custody documentation and the complete raw instrumentation data output of the standards, sample and QC samples analyzed for the project. The quality, bias, and usability of the data are determined based on the criteria set forth in the technical specifications and DQOs of the QAPP, the analytical methods and SOPs used, and theapplicable Regional Data Validation Guidance and Contract Laboratory Program's (CLPs) Functional Guidelines for Evaluating Laboratory Data for Organic and Inorganic Analyses. A full data validation is generally conducted for primary and secondary data that will be used for major Agency decisions that are very likely to have legal implications like the Hazard Ranking Scoring (HRS) for National Priority Listing (NPL) of the site, remediation clean-up goals, source controls and potentially

responsible party (PRP) searches. The RQAM and/or designee performing a full data validation must prepare a formal QA memo identifying the QA discrepancies observed and their subsequent effects on the quality and usability of the affected data.

Technical Systems Review (TSR)

TSR evaluates aspects of the actual performance of the EDCAs, and the implementation and effectivity of the QA/QC activities which includes field and laboratory performance review and assessment. TSRs of Superfund contractors like Remedial Action Contract (RAC), ESAT, Superfund Technical Assessment & Response Team (START) and PRPs are coordinated, scheduled and conducted by the RQAM, QAS and/or designated technical specialists and the RPOs/RPMs on as per request basis, such as before the project starts or when problems are identified through data validation. Laboratory TSRs are performed on Superfund's CLP laboratories located within the Region at least once per year. State, Tribal and Territory drinking water laboratories certification and TSRs are conducted every three years by the Regions Certified SDWA Auditors. The RQAM and/or designated technical specialists also perform TSRs of commercial laboratories contracted by the PRPs, Federal facilities, RCRA owner/operators, National Pollution Discharge Elimination System (NPDES) dischargers and the Underground Injection Control Program upon request or as needed by the RPOs/RPMs. TSRs of internal programs and external organizations will be conducted by the TSR Team in a manner and frequency detailed in Section 9.3 of this QMP.

3.0 PERSONNEL QUALIFICATIONS AND TRAINING

3.1 Technical Proficiency and Quality Requirements at the Organization, Program, and Project Levels

The Human Resources Office (HRO) conducts both employment and training activities for the Region, based on expressed management needs. Management defines the duties, responsibilities and required performance levels for personnel involved in environmental programs and data collection. This is to ensure that personnel have the needed academic background, training and experience to fulfill the necessary function. HRO experts then translate these requirements into the appropriate position classifications and grade levels.

Technical staff are generally hired under scientific classifications: environmental scientists, life scientists, environmental engineer, chemist, etc. The knowledge and qualifications necessary to receive these designations are dictated by Federal Office of Personnel Management classification standards.

The knowledge and certifications for technical personnel performing certain duties are further specified by Agency directives:

- Compliance inspectors/field investigators (personnel who conduct field activities that may lead to or support enforcement actions) (EPA Order 3500.1).

- Contract managers (EPA Contract Management Manual, Chapters 7 and 8).

- Health and safety (EPA Orders 1440.2 and 1440.3).

Technical Training

Training requirements for technical staff generally are specified by Agency directives as prerequisites for certification. Supervisors may specify training for individuals on a case-by-case basis. Staff members also have individual responsibility for maintaining and expanding their qualifications. Each office has been requested to designate a training contact who organizes training to meet the program's needs. Training courses developed to comply with regional policies are generally non-technical, in areas such as cultural diversity.

Professional Development Training

To encourage professional development beyond initial qualifications, HRO sponsors training to maintain or increase the work effectiveness of technical employees. The Regional Training Catalog identifies the following training categories:

- Communications
- Office of Civil Rights
- Management Development
- Financial & Contract Management
- Personal & Professional Development
- Legal & Regulatory
- Health & Safety
- Human Resources Development
- Science & Technology
- Information Systems Technology

Regional management supports the belief that regular training is needed to maintain and improve performance by providing training information, and by paying costs of training taken in-house and also at external institutions. Rotational work assignments, such as the Intergovernmental Personnel Agreement Act (IPA) and career rotation programs, are also encouraged.

3.2 Responsibility for Providing Regional QA Training

Training, although resource consuming, is a necessary component of the RQAM's responsibilities, as many of the RPOs/RPMs and contractors lack the experience and training to personally carry out technical duties, or are reluctant to take ownership of QA functions.

Technical specialists involved in providing training are usually those experienced in performing the function for which training is being provided (i.e., QA review, data validation, sample collection,

custody and shipment, project reporting limits, analytical methods and QA oversight).

3.3 Identification of Training Needs

The primary means for identifying training needs are through the audit process, surveys, and one-to-one discussions between the RQAM and the programs. Training priorities are jointly developed and negotiated by the RQAM and the program offices as part of the annual QAARWP development.

3.4 QAS and Technical Specialists' QA Training

QAS and technical specialists consist of environmental scientists, chemists, engineers, and life scientists. QA Training for technical specialists is encouraged by the RQAM to keep them abreast of innovations affecting their areas of responsibility.

RQAM designated technical specialists who conduct the majority of the QA review functions or oversees the contractor's performance of those activities, become qualified primarily through previous laboratory workbench and instrumentation experience and concurrent work assignments with experienced staff members.

3.5 Regional QA Training

Basic QA training is included in the 4-day Basic Inspectors Training Course required to be taken by all regional staff involved in EDCA. This training introduces the staff to the regional QA policies, QA guidance documents, the required QA-planning documents prior to data collection activities and the Regional QMP available on the Region 10 website. The RQAM and/or QAS also present QA workshops, open houses, and training as needed or upon request. In addition, a basic on-line QA training module shall be developed by the RQAM and the regional technical specialists. The RA through the QA re-commitment letter will require all regional staff to take the QA on-line training on an annual basis. The RQAM and/or QAS may provide training to Regional staff, representatives of other federal agencies, state grant recipients, and Indian tribes on QA-related topics including but not limited to:

- orientation to QA management,
- preparation of QMPs, QAPP, and navigating the review and approval of these documents,
- DQOs,
- sample collection, sample packaging and shipping, paperwork for sample collection,
- data generation and acquisition,
- assessment and oversight,
- data validation and usability,
- QA oversight activities.

3.6 Documentation of Training

The Region's industrial hygienist and Health and Safety Officer and HRO is responsible for maintaining personnel training records. Training completed is documented on EPA form SF-182, which is maintained in the employee's personnel file. The effectiveness of the training is assessed by HRO's review of the course evaluation portion of the SF-182 and by the supervisor's observation of work performance. Course evaluation forms are used to provide feedback to course instructors.

3.7 Access to QA Information

Region 10's OEA website contains a considerable amount of QA material, as well as, links to other useful QA sites (including OEI-QS site). Access to Region 10's OEA website can be from the intranet for internal users, but also from the internet for outside users (i.e., contractors, PRPs, etc.) The webpage connecting directly to the Region 10 QA documents and links is located at: http://yosemite.epa.gov/R10/OEA.NSF/af6d4571f3e2b1698825650f0071180a/802da79dec1942b288256b58000436e9?OpenDocument. A listing of the contents accessible is as follows:

EPA Order 5360.1A2
EPA Quality Manual for Environmental Programs
QA/R-1: EPA Quality Systems Requirements for Environmental Programs
QA/R-2: EPA Requirements for Quality Management Plans
QA/R-5: EPA Requirements for Quality Assurance Project Plans
Analytical Methods

USEPA CLP Contract Laboratory Program (CLP), a listing of several CLP Guidance Documents:

National Functional Guidelines for Organic Data Review
National Functional Guidelines for Inorganic Data Review
Sampler's Guide to the Contract Laboratory Program

4.0 PROCUREMENT OF ITEMS AND SERVICES

4.1 Procurement Activities

The procurement activities in the Regional Office consist of purchases acquired on the Government Purchase Card or Procurement Request (PR). Most items and services not more than $2,500.00 can be purchased via Government Purchase Card by an authorized Purchase Card Holder **(For purchases/services involving EDCAs, the QMPs, QAPPs and SOWs must be submitted to the RQAM for review and approval)**. Procurement Requests are required for all items and services

over $2,500.00. The Contracting Office for these procurements are located in Region 7 or Headquarters depending on the type of procurement. Each requesting program office is responsible to obtain appropriate approvals and funding prior to submitting the procurement request to Region 7 or Headquarters.

4.2 Contracts Involving Environmental Data Collection Activities

The Program Office first identifies its needs and develops the technical specifications, SOW, deliverables, evaluation criteria, and other certifications required. **(For contracts involving EDCAs, the QMPs, QAPPs and SOWs must be submitted to the RQAM for review and approval.)** These requirements are documented on an electronic Procurement Request Form with attachments which is electronically reviewed and approved by the Unit Manager and the Office Director, and funded by the appropriate Funding Control Officer (FCO). The approved and funded PRs are submitted to the appropriate Contracting Office. Changes to procurement documents undergo the same electronic review and approval sequence.

Whether the procurement is to be made at Region 10's, Region 7's, or Headquarter's level, each procurement is processed according to Federal and Agency regulations detailed in the Federal Acquisition Regulations (FAR), EPA Acquisition Handbook, EPA Contracts Management Manual, and the Procurement Policy Notice (PPN) No. 01-02, *"Guidance for Use of Higher-level Contract Quality Requirements in Acquisitions," 03/01* which provides guidelines for addressing EPA's quality requirements for environmental data collection and use. This PPN utilizes a new FAR clause, FAR 52.246-11, for EPA's higher-level contract quality requirements and was developed by the Office of Acquisition Management to update the quality requirements formerly defined in EPA Acquisition Regulations (EPAAR) 1546.2. The procurement process for PRs is documented in the contracts file and the appropriate Office FCOs in Region 10.

When EDCAs are performed by contractors, QA requirements are integrated into the SOW. It is communicated by the Program to the contractor that an RQAM-approved QMP should be in place, and an RQAM-approved QAPP is required every time a new sampling and analysis activity is involved. In most cases, a QMP and a blanket QAPP is due with the proposal or immediately (within 30 days) after contract award. As each task is assigned, the appropriate QA planning document is generated under the task and forwarded by the Work Assignment Manager (WAM), Task Monitor (TM) or RPO/RPM to the RQAM for review and approval. The RQAM and/or designee shall work with the WAM by providing comments and recommendations for the revisions of un-approvable QA documents. Once the RQAM approved the QA planning document, the WAM, TM or RPO/RPM has the immediate responsibility for performing project oversight to ensure that the activities covered in the QA planning document are adequately and effectively implemented. When subcontractors are

used, the acquisition regulations require that responsibility to be maintained by the prime contractors, therefore, no EPA oversight is required.

4.3. Grants and Financial Assistance Agreements Involving Data Collection Activities

Region 10, as do most Regions, provides financial assistance to States, Tribes, Locals and non-profit organizations who assist the Agency in carrying out its mission. Many of the recipients of these assistance agreements perform environmental measurements and, therefore, are required under 40 CFR 31.45 to demonstrate that they have a quality system in place. In order to fund these organizations, RPO must generate a "Funding Recommendation" which authorizes the transfer of funds from EPA to the grantee. These memoranda include a section which discusses the environmental measurement aspects of the project and contain a concurrence block for the RQAM to review and sign for approval.

During these reviews, the RQAM or designee determines whether a grant condition will need a QMP and/or QAPP and/or some other type of a QA planning document to be prepared. If the grant is a continuing one, but no new and/or different measurements are planned, the Decision Memo documents this fact and no condition is placed in the grant. For grant applications involving new measurement activities, conditions in the Funding Recommendation shall state that no environmental measurements are to take place before the QA planning documents are approved by the EPA RQAM. The Grants Office use the Inter-agency Grant Management System (IGMS) database to track the review and funding status of the grant applications received in Region 10.

The grantee and the RPO work together to determine when the preparation of QA Planning documents is required. These QA documents are submitted to the RPO. The RPO is responsible for ensuring that the QA planning documents submitted are adequate in meeting the Program goals and objectives. The document is then forwarded to the RQAM for QA review and approval/disapproval. Once the RQAM completes the review and approval of the planning document, immediate oversight responsibilities are transferred with the PO, Task Monitor or the WAM.

4.4 Oversight of Quality

The EPA WAM, TM or RPO/RPM for the contracts and RPOs for grants and interagency agreements establish the framework for monitoring the quality of items or services by incorporating inspection and acceptance criteria into contract statements of work or work plans for grant/interagency agreement. They are responsible for oversight and for ensuring that products delivered meet contract and grant/interagency agreement requirements.

Oversight of contractor QA products is accomplished mainly by the efforts of the RQAM, QAS and/or designated technical specialists comprising the QA Review Team (QRT). The QRT reviews contractor quality planning documents to ensure that Agency policy and contractual requirements related to QA are being met. The QRT members generate comments and recommendations through a QA memo as

a result of the review of the contractor's QA documents. The QA memo is sent by the RQAM to the WAM, TM or RPO/RPM or other federal Agency POs responsible for the management and oversight of the particular contract or work assignment. The POs/RPMs then communicate the QA comments to the contractor. The contractor shall revise the QA document and provide the POs/RPMs and RQAM a written response stating how the comments and recommendations were addressed in the revised QA document. Review, comment and revisions continue to cycle until the RQAM and the QA Review Team approve the QA document.

5.0 DOCUMENT AND RECORDS

Records management programs for Region 10 provide SOPs and framework to provide records storage and timely retrieval, secure storage and preservation of sensitive records, minimize potential loss or damage to records, and provide cost effective use of available storage space. RQAM designated technical specialists are responsible for ensuring that all QA-related records and documentation are maintained in a proper manner, ensuring compliance with all applicable statutory, regulatory and EPA requirements for documents and records, i.e., EPA Order 2160 (EPA 1984) and the EPA Directive 2100, Chapter 10 (EPA 1998).

Official file copies of program specific approved QMPs, QAPPs, Sample Alteration Forms (SAFs), QAPP addendum, SOPs and applicable Program or Project Specific QM/QA documents related to all environmental monitoring programs within Region 10 shall be maintained by the Regional Program Offices. Officially signed and approved QA documents from the States, Tribes and Local organizations are filed at RQAM files. All of the original CLP- generated data, both hard copy and electronic, shall undergo completion/evidenciary audit, data verification and validation to determine the data's quality and usability. The CLP data are filed in locked file cabinets for a period of 6 months or until the site specific project had been completed. After the project had been completed, and program authorization had been obtained, the CLP-generated analytical data and review documents are transferred to the program for filing or FRC for storage. The establishment and routine use of filing systems and security procedures for the programs are the responsibility of the Regional Program Offices. This section discusses documents and records maintained by the RQAM. The QA work tracking system accurately ensure that QA tasks/work are completed on time and compiles QA work that has already been completed in a database. In addition to this, a bound paginated logbook is also maintained by the designated QAS to track the CLP generated data received and audited in the Region.

All QM/QA guidance, required QA documents and agency orders pertaining to QM/QA activities will be maintained as convenience copies by the RQAM. In addition, the RQAM and the technical specialists will maintain convenience copies of the most current and EPA promulgated methods, Statements of Work, program QA requirements (CFRs) and the most current guidelines for data

validation. These documents are also electronically available at the EPA web site which contains electronic postings of Regional and National QA related documents.

5.1 Security Procedure

For security of physical QA files within the RQAM, access to the 9th floor is limited to those with electronic key cards administered by the EPA (EPA staff, grantees, and in-house contract personnel) and building management (staff with a need for access such as custodial and building management/maintenance staff).

Security procedures for electronic records within the OEA are achieved through the OEA USER\SHARE directory access which is limited to LAN administrators and OEA staff. Access to the OEA USER\SHARE\QA directory (and any subdirectories thereof) is limited to the RQAM and QAS. RQAM approved SOPs, QMPs and other QA documents are maintained on the QA directory. The RSCC tracking system for sample collection and analysis is maintained in the RSCC subdirectory of the QA directory. Access to E-mail messages is restricted by LAN passwords and Lotus Notes Passwords for each individual. The work assignment and/or QA tasks tracking database, regionally referred to as the OEA Lotus Tracking System, is maintained by the RQAM designated QA DCO. Only the work requestors, assigned QAS and RSCC has the authority to delete and/or modify completed QA tasks. The tracking database is available for the Project Officers and Program Managers to request QA assistance, for the RQAM and technical specialists to accept the work, to monitor the expended man hours needed for the task and the status of the task. The RQAM and QAS do not maintain data bases containing environmental data. National and Regional databases are maintained by Environmental Information Unit (EIU) located in OEMI.

5.2 QA Filing System

RQAM Convenience Copy Filing System

The RQAM will retain convenience copies of some of the RQAM approved QM/QA Program Plans, Project Plans, SAPs, QAPP addenda, SOPS and applicable Program or Project Specific QM/QA documents related to environmental monitoring programs within Region 10. RQAM convenience copies are kept in the roll-away file area on the 9th floor, north side. Major file separations are for each state in the region. Within each state's section, documents are filed in the following categories: state QMPs, QAPP, etc., Tribal QMPs, QAPP, etc., contractor, county and municipal non-site specific QMPs, QAPP, etc., and site specific QAPP etc. Convenience copies will not be retained by the RQAM in cases where the project manager asks for the return of the QA documents provided for review. In cases like this, only convenience copies of the QA review memos will be retained in the RQAM correspondence file.

Convenience copies in the QA file system will generally be retained for ten years. After ten years, the RQAM will consult with the program for disposal of the convenience copy. At the time convenience copies are disposed of, the convenience copies of QA memos will be removed and retained in a chronological or alphabetical correspondence file. The RQAM correspondence file will be archived at the Federal Records Center (FRC) on an as needed basis.

RSCC Project Filing System

The RSCC, located in the AMAU, tracks and maintains correspondence/communication and documentation related to environmental data collection projects that are scheduled through the RSCC. RSCC project files are currently maintained on the west side of the 9th floor in designated cabinets. Some very large project files are also maintained in the RQAM roll-away file area on the 9th floor, north side.

When the in-house filing system capacity is exceeded, arrangements will be made to permanently archive older project files at the FRC. RSCC project files generally contain copies of formal requests for laboratory support, CLP lab requests/lab assignment information, project notes (consisting of printed E-mails and/or hand written notes concerning the scheduling and analysis of project samples), excerpts from the QAPP (or in the case of small QAPP, an entire copy of the QAPP), etc. RSCC SOPs contain further details on project files and on the RSCC electronic data tracking system. Electronic copies of RSCC SOPs are stored on the OEA USER\SHARE\QA directory.

CLP CSF Filing System

The technical specialist designated as the QA DCO will be responsible for the receipt and maintenance of CLP sample delivery group (SDG or CSF) files for regional projects. CSF files contain original laboratory data (final and raw data) for samples analyzed via the CLP. While in the possession of the AMAU, CSF files are stored in: 1) locked file cabinets located on the 9th floor, west side, 2) RQAM or data review/validators' offices, 3) the QA DCO's office, or 3) labeled archive boxes while awaiting transfer to the Superfund Records Center (SRC). Upon receipt, summary information for each CSF (e.g., purge file/CSF number (sequential number assigned by the data recipient to each CSF), case number, SDG number, receipt date, lab code, etc.) is recorded in a bound log book.

CSFs to be reviewed by the ESAT contractor are sent to the contractor at the EPA Region 10 Laboratory. The WAM for the ESAT data validation function is the RQAM or a senior QA data validator designated by the RQAM. The WAM keeps track of the status/location of individual CSFs through technical direction task orders. CSFs are returned to the WAM who then forwards a copy of the validation memo and qualified data to the EPA RPMs/RPOs and other QAPP specified data recipients. A copy of the validation memo and qualified data is kept with the CSF, which is returned to

the QA DCO for filing.

After CSF files have been in-house for at least six months, the RPM/RPO is contacted for permission to transfer the files to the FRC. Once permission is received, the files are placed into archive boxes in accordance with FRC requirements. When the boxes are ready for transfer, they are taken to the SRC. Hard copy records of CLP CSF transfer are maintained by the RSCC. The SRC eventually transfers the files to the FRC as permanent records. If the SRC provides the accession information, the RSCC updates the RSCC tracking system to include the accession number and box number out of total boxes for each CSF.

Non-CLP CSF Files

Occasionally, the RSCC schedules analyses of non-Superfund samples via POs. The laboratory services purchased through POs are required to submit original analytical documentation equivalent or similar to the CLP CSF, unless submission of data summaries are specified in the QAPP. Data deliverable requirements are specified in the SOW. Electronic copies of SOWs are stored on the special analytical services (SAS) subdirectory of the QA LAN directory. Electronic SOWs are generally kept for each type of analysis historically purchased via the RQAM and RSCC. SOWs are continually updated/written over for the next project requiring the same analysis. Hard copies of project specific SOWs are stored along with a copy of the RPO in the RSCC project file.

Each RPO laboratory is required to submit a copy of the SOW as part of the CSF. As with CLP CSFs, the RPO CSF receives two types of review: 1) completeness/evidenciary and 2) technical reviews. The RQAM sends a copy of the QA review report and qualified data to the data recipients specified in the RQAM approved site specific QAPP . A copy of the QA review report and qualified data is kept with the CSF. The CSF is transferred to the requesting program once completeness and technical reviews are completed. The requesting program is responsible for the maintenance and disposal of the CSF generated via RPO after it is transferred.

5.3 QA Tracking System

RSCC Electronic Tracking System

The RSCC electronic data tracking system is a relational Approach database system created, maintained and modified, as needed, by the QA DCO. The system is stored under the RSCC subdirectory of the QA directory. This system is purely a tracking system for CLP data packages and summary information for samples scheduled with the EPA Region 10 Laboratory or scheduled for subcontracting by the field support contractor. The system does not contain environmental data.

QA Document Review Tracking System

For tracking QA documents submitted to the RQAM for review and approval, the RQAM utilizes the OEA's Lotus Notes Project Tracking System. This tracking system allows the program RPMs and RPOs to request technical support from OEA and RQAM in the review, assessment and approval of their project-specific QA documents. The project requests are logged-in with the expected deliverables, estimated level of effort (man-hours) and the estimated date of completion. Upon receipt by the QA DCO, the open request is routed to the RQAM and/or appropriate QAS and/or technical specialist(s). Weekly tracking reports are generated by the QA DCO outlining the status of the project request, the level of effort (man-hours) spent and submitted to the RQAM and/or the technical specialist(s) assigned to the project. At the end of each fiscal year, the number of QAPPs reviewed and the data validations completed are summed up using the tracking system. These numbers are reported in the QAARWP.

5.4 Sample Documentation

The RSCC maintains and distributes supplies of sample paperwork related to the CLP. CLP paperwork is obtained by the RSCC through the CLP Analytical Services Support Contract (CLASS) contractor. The RSCC also maintains and distributes supplies of regional sample paperwork which is obtained through Region 10 graphics (via the Government Printing Office (GPO)). If received, copies of completed sample paperwork are filed in the RSCC project file.

Regional Sample Paperwork	
Form	Use
2 part carbonless Analysis Required (currently four types)	Primarily used for EPA Region 10 Lab analyses
3 part carbonless Field Sample Data Sheet and Chain of Custody Form	Primarily used for EPA Region 10 analyses but can also be used for contracted laboratories (via Regional Purchase Order or field contractor subcontract)
2 part carbonless Receipt for Samples Form	Required for use at Superfund sites
Sample Tags (Tyvek tags with stretchable string attached)	Required for CLP use, optional (project manager's discretion) for samples analyzed by non-CLP arrangement.

5.5 Control of QA Guidance Documents

QA guidance documents are developed for Regional use by the RQAM and technical specialists in the absence of Agency-wide guidance, or when detailed Regional processes need to be documented. Examples include Regional Guidances for Data Deliverables for non-CLP laboratory data packages,

WPs, QAPPs, SAPs and FSPs for Superfund investigation and clean-up activities, and Generic QAPP for Program Compliance Inspections.

Regional QA Guidances are prepared by the RQAM, QAS and/or the technical specialists experienced in the subject area covered. Generic QAPPs are reviewed by the RQAM and/or other subject-area peers before approval by the RQAM and Program distribution. Document control format is used, and unique document control numbers are assigned to each document. Revisions are prepared and transmitted as needs are identified by the technical specialists. Regional guidances are available at the OEA\USER\SHARE\QA directory.

6.0 COMPUTER HARDWARE & SOFTWARE

6.1 Regional Information Resources Management Policies

OMEI has the primary responsibility for setting policy and guidance for the management and development of computer-related program support in Region 10. The Director of this Office directs the Information Resources Unit (IRU) and EIU responsible for the Local Area Network, Geographic Information Systems, database management, information security, personal computing and information access, application development, desktop support, training, and records management. Personal Computing/Local Area Network coordinators in each Office act as liaisons between IRU and their office co-workers.

Some of the program offices have their own database administrators who coordinate activities relating to their associated databases. Since these databases are national databases, requirements are defined by the national program offices at HQ. Regional data are collected, processed, and managed by the program offices. IRU manages the hardware, software and networking platforms. IRU also coordinates with the program offices on hardware and software issues, purchases and upgrades, and pilot programs.

EPA's Information Technology Architecture Road Map is an organized collection of products and technologies that define the standards and guidelines supporting the technical design of Agency information systems. Furthermore, the Agency's Information Resources Management (IRM) program is subject to the Information Technology Reform Act of 1966 (Division E of Public Law 104-106). Region 10 IRM follows Agency-wide guidances: *"System Design and Development Guidance," "Supplemental Guidance to EPA's System Design and Development Guidance," "Operations and Maintenance Manual,"* and *"IRM Policy Manual."*

OMB Circular A-130 No. 4 requires all federal agencies have an information security program. The issue of information security pervades all aspects of the Agency's information technology infrastructure. An information security program that is consistently administered across the entire Agency is critical to

the Agency's ability to sustain and maintain its ongoing operations. The Agency must achieve an appropriate balance between providing safe access to accurate environmental information and protecting the information assets of the Agency.

6.2 Use of Computer Hardware and Software

The purchase of computer hardware and software by Region 10 and its contractors is governed by EPA Orders 2100.1 (Accessible Electronic and Information Technology Policy) and 2100.2a1 (Information Technology Capital Planning and Investment Control Policy). These Agency policies are designed to ensure that the computer hardware and software used meet program requirements, and are consistent with the Agency-wide standards they cite. The Agency adopted policies which treat "de minimis" personal use of office equipment by Federal employees as an "authorized use" of Government property under 5 C. F. R. 2635.101(b)(9) and 2635.704(a).

6.3 Assessment of Impacts of Hardware and Software Changes

Most requests for computer system development, maintenance, enhancements, etc. are initiated by clients in the program offices through their personal Computer Coordinators. IRU works closely with the office's personal computer coordinators to determine the clients' needs, options and implementation schedule.

Success or failure of system developments is measured by the level of client satisfaction. IRU has various mechanisms in place to monitor customer satisfaction, including surveys, outreach meetings to discuss IRU-related issues, solicitation of client feedback and resolution of differences, and an open-door policy.

The assessment of the potential impacts of IRM changes is emphasized before implementation. Broad-based projects impacting the entire Region generally require support by the SIRMO.

Process, Roles, and Responsibilities for Developing and Evaluating Software

OEI has published several documents that provide the basis for developing and evaluating software. These documents as listed are used, as appropriate, to develop and evaluate software:

EPA Directive 2182 - System Design and Development Guidance (April, 1993)
http://www.epa.gov/irmpoli8/sysdesn/

Web Guide: Application Deployment
http://www.epa.gov/webguide/deploy/index.htm l

Information Technology Architecture Roadmap
http://basin.rtpnc.epa.gov/ntsd/ITARoadMap.nsf

6.4 Standards for Computer-Generated Data

Regional IRM data standards are consistent with Agency-wide standards: Corel Wordperfect (word-processing), Oracle (database management), Lotus 1-2-3 (spreadsheet), Lotus Notes (communications), and ARCInfo (GIS). Regional contracts require conformance with the Regional and Agency standards for hardware, software, and data delivery format. Seven-point justifications for computer- related purchases require IRM concurrence. The monitoring of compliance is the responsibility of POs.

6.5 Regional Environmental Data Storage and Retrieval

Monitoring data are in some instances, are stored on computer databases. Some are databases developed by HQ program offices (e.g., Store It and Retrieval [STORET] for water program, Aerometric Information Retrieval System [AIRS] database for the air program) while others are developed for specific users (e.g., Superfund contractor data from remedial investigations, LIMS system for the MEL and the PM2.5 Evaluation Database (PED) for the PM2.5 Weighing Lab). The database software includes QA routines. These routines are assumed by the user to be adequate for the intended use of the database. The responsibility for QC of data entry and corrections belongs to the program offices which maintain the databases.

Process, Roles, and Responsibilities for Verifying that Data Being Compiled and the Quality Control and Maintenance that these Data are Appropriate for Intended Use

OEI has published several documents that provide the basis for data elements. These documents are as follows:

Environmental Data Registry (EDR) http://www.epa.gov/edr/

EPA Directive 2190 - Privacy Act Manual http://www.epa.gov/irmpoli8/privacyact/

EIU uses these documents, as appropriate, to review data and data elements used in data assessment, data mapping and modeling.

Process, Roles, and Responsibilities for Developing Procedures to Ensure that Historical Files Are Documented and Can Be Recovered

U.S. EPA Directive 2100 - IRM Policy Manual- Chapter 10 - RECORDS MANAGEMENT July 1996 http://www.epa.gov/records/policy/2100/2100-10.htm

EPA Records Schedules http://intranet.epa.gov/records/schedule/index.htm

The documents referenced above provide the guidance that is used by the owners of the official records. They are responsible for ensuring that their historical files are properly documented and conform to official Agency records disposition schedules.

7.0 QUALITY PLANNING

7.1 Management of Systematic Planning

The primary vehicles for annual planning in the Region are the budget process, GPRA and the State/EPA Agreement process. Depending on the sensitivity and level of work that may be involved, sites are prioritized by the RA/DRA. The DRA allocates resources to each office for the management and operation of specific programs, based on the Region's anticipated budget. Program managers balance their available resources with their projected need for support, e.g., QA and technical support from OEA and other Regional Offices to meet GPRA and program goals and commitments. Programs' full time employee (FTE) distribution (in terms of man-hours) in the Region's Technical Support Offices are revisited and negotiated. Acceptance of the program's proposal for FTE distribution results in work commitments.

Most regional work activities are mandated by policy guidance, congressional initiatives, commitments to HQ, and Program Office Work Projection Plan (WPP) prepared by each Program Office prior to the start of a fiscal year. It contains estimates of the work activities for that year. Ideally, the WPP is developed in consultation with the Program Offices' technical support offices. The RQAM seeks input from the offices it supports in preparing the QAARWP prepared for each fiscal year.

7.2 Elements of Systematic Planning

The QS tools used for systematic planning consists of the conceptualization and preparation of project specific WPs, QAPPs, FSPs and SAPs, SOPs and establishment of DQO goals. These tools are discussed in section 2.3.

8.0 IMPLEMENTATION OF WORK PROCESSES

Section 2 describes the implementation of work processes in the Region.

9.0 ASSESSMENT AND RESPONSE

All environmental data collection activities require a mechanism for monitoring the effectiveness and adequacy of the QA measures integrated into the program. The standard oversight mechanism used by

the Region is the quality assessment, review or audit. The basis of the reviews are the approved planning documents identified in section 2.3. A review compares the data quality needs of the program and the documented procedures for obtaining the data against what is actually implemented and the resulting quality of the data obtained. The review can pinpoint the weak link in the data collection activity, whether it be at the managerial, sample plan preparation, sample collection, analytical, data review, or data usage stages.

Overall, the outcome of a review is expected to: (1) identify strengths and weaknesses, (2) cause corrective actions to be taken to alleviate problems, (3) facilitate the initiation of changes to enhance the QA program, (4) serve as a vehicle for providing technical assistance, (5) enhance awareness and understanding of QA/QC policies and procedures and (6) provide a measurement of the effectiveness of QC in assuring the quality of data.

Reviews include the TSRs and QSRs of program, field and laboratory operations and functions. These reviews are performed by the RQAM, QAS and/or the designated technical specialists on the regional programs on as needed or as per program request basis. The QSR and TSR of the Regional Laboratory Program are conducted every two years by the RQAM and designated technical specialists and National Exposure Research Laboratory (NERL) - Cincinnati, respectively. QSRs of State agencies and programs are performed by the RQAM and the designated technical specialists every three years. Quality assessments or audits are intended to provide an overview of the effectiveness of the QA measures adopted by each program and/or organization. The majority of technical specialists are technically versed in one or several of the chemical, physical or biological sciences, engineering and statistics. The expertise and experience of the auditors will be matched with the activity being reviewed, this will help to avoid challenge to the validity of audit results. Auditors will have audit training and certifications (when required) on conducting QSRs, TSRs, SDWA and NELAC certifications and other relevant experience to enable the performance of effective reviews. Auditors shall also be experienced and proficient in applying QA in every EDCA, working knowledge of the organization and operations being reviewed is also desirable. Prior to audits being conducted, internal clearance and authorization to perform the audit will be obtained, communication with the organization to be audited on the scope of audit and agreement on how the audit will be conducted (orientation briefing, interviews, exit briefing, followed by draft report, final report, etc.) will also be performed. Up-front planning will help to ensure appropriate individuals and records are accessible during the audit, etc.

In most QSRs, auditors will be selected from the organization being reviewed (e.g., the QA Officer) to participate in or observe the audit. The selected individual should be independent of any unit under review to maintain objectivity.

9.1 Review of QA Planning Documents

All requests for technical support for QA planning, implementation and assessment shall go through the RQAM. At the beginning of each fiscal year, the RQAM through the QAARWP shall identify the number of FTE QA support that will be needed in the implementation of the region's QM and QS for the following fiscal year. The main bulk of QA support for the RQAM is organizationally located in OEA's Technical Support Unit. However, expertise in other scientific may also be requested by the RQAM from the other OEA Unit Managers. QA Review Team (QRT), comprised of the RQAM, QAS and/or other technical specialists, is responsible for reviewing all QA planning documents submitted to the RQAM for review and approval. The RQAM has the responsibility for ensuring that the QRT members are properly trained and are very knowledgeable of the QA and technical requirements of various programs and regional QA document guidances for projects involving EDCAs. The members of the team must be consistent in the interpretation and application of these guidances, and must ensure that the QA review memos share a common format. Junior document reviewers are initially trained by performing parallel and joint reviews with a more senior QA document reviewer or RQAM until such time that it can be demonstrated by the junior reviewer that he/she understands how to apply and interpret the appropriate guidance. To ensure uniformity and consistency of QA reports, the QA review memos are peer reviewed by another QA document reviewer. Depending on the sensitivity of the QA issues, the team members are empowered and authorized to sign their own QA review memo's routed through the RQAM for concurrence and approval.

During the course of the review, the reviewer assesses whether the document is consistent with the National QA guidance, determines whether the proposed QA/QC activities, the target compounds, reporting limits and analytical methods will adequately support the program and the project's established DQOs. The reviewer also ensures that all aspects of the program are described and that all measurement activities are covered by the QA planning document. This means that the technical and QA activities must agree and jointly support the intended use of the data. The QA review of the QA planning documents are performed following the flowchart illustrated in Figure 3.

In cases wherein the authority to review and approve QA documents is given to the State, Tribe or Local organization through EPA's approval of their respective QMPs, the RQAM must ensure that the review system defined in the State, Tribe or Local organization's QMP is adequate, sufficiently rigorous and will meet EPA's QM and Q.S. standards. RQAM's approval of the organization's QMP carries with it an endorsement of the QM and Q.S. of the organization, and hence, a delegation of QA implementation responsibility to the organization. If the project is part of an EPA blockgrant for delegated programs or an EPA contract with a State organization, the State will perform the QA review, subject to having an approved QA system defined and approved by the RQAM, otherwise the RQAM and/or designee performs the review. Delegations of QA responsibilities are also subject to

having professional skilled QA personnel in the organization who will be responsible for the performance of all QA related responsibilities described in the organization's QMP. Usually, if the project or task assignment under a contract is funded directly by the EPA programs, the RQAM and/or designee performs the review of the QA documents.

The standard turn around time for QA document review is 14 days. This turn around time may be subject to change depending on the regional priority settings, availability of resources, number of documents requiring review and completeness of the QA documents submitted for review.

9.2 Quality System Reviews (QSR)

In order to assess whether the goals of the Agency's mandated Quality System have been met, the RQAM conducts periodic QSRs to evaluate the effectiveness of the QA program implemented in the Region and States. They are further used to evaluate whether the documented Quality System is in conformance with what is actually implemented. The management and technical activities associated with implementing QA and QC for ensuring the collection of data of known quality are reviewed, along with the roles, responsibilities, and authorities of the individuals implementing the Quality System.

QSRs are meant to ensure that an organization has an effective QA System in place and that it is provided the necessary resources and qualified individuals to enable it to generate data of known quality. The QSRs obtain an accurate description of staff understanding of QA roles and responsibilities and staff skills and knowledge of QA practices and principles required for effective execution of QA activities. The QSRs also evaluate adherence to the Region's QA documentation requirements. QSRs further reveal the proficiency of the Region's QA system in auditing, identifying errors and rectifying QA/QC deficiencies.

QSRs will be conducted for both EPA and non-EPA funded environmental data collection activities in which EPA has an oversight responsibility or uses the environmental data for decision making purposes. EPA funded data collection activities include work done under cooperative agreements such as grants and IAGs. For non-EPA funded activities conducted by external programs such as Federal facilities, these organizations maintain primary responsibility for assessing their Quality System. It is required that the Federal facilities QSR report be submitted to the EPA for review and comment. QSRs of non-EPA funded activities assesses EPA's QA oversight responsibilities.

The Regional QSRs will be conducted in accordance with the "*Guidance for Preparing, Conducting, and Reporting the Results of Management Systems Reviews (EPA QA/G-3)," January 1994*. At a minimum, one QSR will be performed on a Regional program, Regional Laboratory and on EPA funded State Program every three years. However, QSR will be triggered by severe and persistent

QC failures or non-compliance identified through data validation process, routine and standard field/lab audits and other quality checks.

QSRs will be conducted by the RQAM, QAS and/or the designated technical specialists. The review process begins with the RQAM contacting and coordinating with the management of the office and/or state to be audited. Through a formal EPA letter, the RQAM informs them of the audit to be performed and the purpose of the QSR. Participation by non-QA regional staff members like the laboratory personnel will be encouraged and agreed upon by the RQAM and the office with which the QSR will be conducted. When performing QSR on programs in the Region, non-QA staff will be selected from programs other than that which is being audited. When the states are audited, non-QA staff members directly related to the State program being evaluated will be allowed to participate in the QSRs.

Following the agreement between the RQAM and the office to be reviewed, the audit is scheduled and performed by the RQAM. The QSR team, comprised of QA and, in some cases, non-QA staff, will prepare a draft summary report to be submitted to the Director of the Office in which the audited program is located, and to the organization's RA/DRA within 30 days of the audit date. The report resulting from an QSR will describe when, how, and by whom the audit was conducted, what specific items were reviewed, a summary of audit findings (overall program assessment and significant findings), and recommendations for corrective actions as necessary. The Program Managers and/or State agency prepares a response to the recommendations contained in the QSR report within the time frame agreed upon between the RQAM and the program or State. The report is finalized upon receipt of a response from the organization reviewed. The organization reviewed is then responsible for ensuring that prompt corrective action takes place on any findings made. The RQAM may conduct follow-up on the implementation progress of corrective actions at least one year after submission of the agreed upon corrective actions.

9.3 Technical Systems Review (TSR)

The difference between TSR and QSR is the fact that TSR evaluates the actual data collection aspects of the environmental data collection activities. QSRs primarily address the management controls integrated in the organization to ensure that data collection activities produce the data quality needed by an organization. TSR review includes, but is not necessarily limited to:

- field and analytical procedures,
- planning documents (QMPs, QAPP, QA Manuals, SAPs, FSP, etc.) ,
- calibration records,
- QA/QC criteria compliance and records ,

- sampling and measurement procedures,
- SOPs,
- personnel qualifications,
- Laboratory QA Manual,

Field audits are conducted to verify that sample collection, shipping, and associated procedures are consistent with those specified in the QMP, QA Manual, QAPP and/or FSP. The actual frequency of conducting TSRs depends on the regional priorities and availability of QA and other technical staff resources.

On-site TSRs of CLP laboratories located in the Region are conducted by the Regional CLP PO at the beginning of a contract or on as needed basis. Standard CLP audit checklists are used, in conjunction with on-going reviews of data validation reports and other contract compliance information. The evaluation reports from these audits are used to identify and remedy laboratory performance problems. Repeat audits are made on an as-needed basis to resolve laboratory problems. When problems are identified, the CLP PO oversees the implementation of laboratory corrective action or contract action if necessary. Note that if no laboratories within Region 10 are currently under contract to EPA, the CLP PO may be requested to audit laboratories in other Regions. This effort, however, is outside the scope of this QMP, as it is conducted in response to requests from Superfund staff at Headquarters.

TSRs are conducted on non-CLP laboratories including those used by Superfund PRPs and Federal Facilities, RCRA owner-operated laboratories, and others, according to an audit strategy, or as requested. The CLP audit checklists are used as the basis for performing these audits.

Laboratory certification TSRs of State, Territory, and Tribal drinking water laboratories are conducted by the SDWA Certification Officers from MEL once every three years. In addition, annual overviews of certification audits of private laboratories by State certification staff are also conducted. Procedures and checklists for these audits are defined in the laboratory certification manuals published by the National Environmental Research Laboratory (NERL) - Cincinnati.

Both field and laboratory TSR reports describe when, how and by whom the audit was conducted, the specific analytical procedures reviewed, a summary of the findings, and recommendations for corrective action. The TSR report is transmitted to the audited office, the program manager, the RQAM and the RPO, as appropriate. The audited organization is responsible for ensuring that prompt corrective action takes place. Follow-up activities vary with the program requirements.

9.4 Performance Evaluation

Performance evaluation samples (PES) assess the ability of an analytical system to obtain accurate and reliable data. It consists of providing reference or PES to the laboratory for analysis. The PES are prepared using media that most closely resembles the samples being collected from a site (e.g., soil, water) and spiked with known concentrations of chemical constituents or pollutants of concern. The analytical results obtained by the laboratory audited are compared to the known concentrations of the specific parameters contained in the PES to determine if the laboratory properly identified and quantified the constituents within established or calculated control limits. The RQAM encourages project managers and their contractors to include PES and standard reference materials (SRMs) in their QAPP, SAPs, and FSPs. Regional guidance on the use of PES is available from the RQAM.

PES and SRMs of specific parameters are obtained from appropriate laboratories by RQAM when needed by the RPMs/RPOs to monitor laboratory performance. Regular infusion of blind PES into the sample stream has been an effective method of quality control for field and laboratory procedures. For example, routine use of PES in on-going monitoring activities not only provides insightful understanding of project data quality, it also helps to reduce the amount of data review otherwise needed. All laboratories involved in the CLP are required to analyze Quarterly Blind Samples (QBS) for performance evaluation. In special situations, the RQAM prepares PE samples from neat materials supplied via the Superfund QA Technical Support Laboratory in Las Vegas. These samples are taken to the field and submitted blind or double-blind with field samples, to the laboratory. Results and/or data packages submitted to the RQAM by the subject laboratory are evaluated for consistency with pre-established acceptance windows. A written report describing the assessment and implications is submitted to the client. RPOs/RPMs are responsible for ensuring that appropriate and prompt corrective action takes place, assistance is provided by the RQAM upon request.

The laboratories within the Region participate in Performance Evaluation Studies (PES) for the Agency-wide Public Water Supply and NPDES programs certification compliance. The State Laboratories are certified by the EPA Certification Officers, thereafter, giving the States the authority to Procedures for these evaluations are dictated by NERL-Cincinnati and the National Institute of Standards and Technology (NIST). Laboratories which exceed the statistical acceptance limits are requested to evaluate the source of differences and report their corrective actions to the Region's SDWA certification officers.

9.4 Data Quality Assessment and Data Validation

Discussed in Section 2.3.

10.0 QUALITY IMPROVEMENT

Continual improvement is achieved by constant evaluation of program, project and individual performance in terms of ever changing environmental policies, objectives and regional budget allocation.

Program improvement and quality management for Region 10 and its programs is not accomplished by only the RQAM, QAS and the technical specialists. It requires the sustained commitment of all levels of management to emphasize and encourage continuous improvement by staff in their development and implementation of projects, initiatives, and on-going programs. The quality system established by this QMP is the responsibility of all Region 10 employees. Quality improvement must be considered, and must be incorporated into the everyday, on-going work of the Office.

The role of the RQAM, QAS and technical staff is to provide technical assistance to the various units of the program as they initiate projects and to review and comment on the processes that exist or processes which do not incorporate the quality objectives of the Region. The RQAM and QAS shall meet regularly to discuss cross-cutting issues and to look at ways of improving the organizational implementation of QA. The RQAM and QAS shall also provide a perspective on the continuous improvement process and provide advice and recommendations to program office managers on ways to improve the quality processes within the Region.

10.1 Quality Improvement Process

It is the responsibility of line management for assuring staff participation for all program reviews and to review annually all QA activities of their staff, e.g., determining that SOPs are in place and revised if necessary, that QAPPs are written and approved in advance of project start-up and that data quality assessments are made. All deviations and discrepancies noted during any independent or self-assessment review will be corrected promptly and modifications made, if necessary, to the Regional QMP. Additionally, the RQAM communicates results of audit, assessments, and reviews with program counterparts to identify areas of excellence, and areas needing corrective actions.

10.2 Effective QSRs and TSRs conducted by RQAM

As discussed in Sections 9.1 and 9.2, QSRs and TSRs will be conducted to check the performance of the program, organization and/or offices performing environmental data collection activities within and for Region 10. Field and Lab audits will also be utilized as a preventive measure to ensure data collection and generation conforms with approved QA documentation and are capable of generating data of known quality. It is expected that when deficiencies are identified, effective corrective action is expected to be completed and documented by the responsible project officer or manager.

10.3 QSRs Conducted by HQ Quality Staff (HQQS)

The RQAM relies on the QSRs conducted by HQQS every three years on the Region's QS to contribute towards its continual quality improvement. The HQQS review is based on the QS described in this QMP. The QSR assesses the effectiveness of the Quality System implemented in the Region and verifies conformance of the implemented system with what is documented in the QMP. HQQS identifies areas of QA vulnerability in the Region and ensures that these concerns are adequately addressed by the RQAM and the QAS. The RQAM also works with the offices in responding to the comments, in cases where joint responses are needed.

10.4 Effective Communication and QSRs

Direct communication with organizations responsible for performing environmental data collection activities is a two way process and a necessary tool for the RQAM in detecting and preventing data quality problems. These quality problems may be related to the services provided by the organization, or more systemic problems which affect an organizations ability to produce data of known quality.

The authority of the RQAM is relied upon by the programs and regional partners to point out the necessary corrective actions needed to address any QA vulnerability that may arise in environmental data collection activities conducted in Region 10, external agreements, regulatory processes, or day-to-day operations (e.g., use of non-approved methods for Clean Water Act compliance monitoring by a State program). Once a QA weakness has been identified, either by the program or RQAM and the QRT, they meet with the organization's senior management to work on a mutually acceptable resolution. The resolution is retained by the RQAM in a policy, memorandum of agreement or planning document. Follow-up is performed by the RQAM or designee with the organization to ensure that the resolution reached has been implemented.

Similarly, when the program or a partner to the Region communicates that QA vulnerability exists within its program or the program it oversees, the RQAM or designee may elect to perform a review. The different types of QA reviews used for quality assessment conducted in the Region are discussed in Section 9.0. The QA planning documents, also discussed in Section 2.3, form the basis for performing the reviews. Upon completion of the review, offices or responsible organizations are expected to address any audit findings in writing, documenting the corrective measures to be implemented. Follow-up is performed by the RQAM or designee with the organization to ensure that the resolution reached has been implemented.

10.5 Implementation of Corrective Action on Deficiencies Identified through Audits

If the RQAM and audit team identify vulnerabilities through the audit processes, these vulnerabilities will need to be addressed by the respective office or organization audited. The RQAM will follow-up with the respective office or organization to ensure that a corrective action plan is developed and implemented by the office or organization to correct and/or resolve the vulnerability addressed in the audit report. Where concerns remain unaddressed, the RQAM may elevate the vulnerability to an OD as discussed in Section 1.5 of this QMP.